

**Michigan Title X
Family Planning Program
Standards & Guidelines Manual
2021**

Michigan Department of Health and Human Services

April 2021

TABLE OF CONTENTS

Introduction to the Document

Introduction	7
--------------------	---

I. Federal and State Legislation, Requirements and Resources

A. Federal Legislation, OPA and HHS Regulations and Resources

1. Title X Family Planning Program.....	9
A. Title X Statute	10
B. 42 CFR Public Health Part 59 Grants for Family Planning Services.....	14
2. Title X Federal Program Guidelines, Guidance and Resources	
A. Program Guidelines, Tools and Documents	27
B. Program Priorities, Key Issues and Legislative Mandates	28
C. Title X Program Description	29
D. OPA Program Policy Notice PPN Series	
OPA PPN 2016-11 - Integrating with Primary Care Providers.....	31
OPA PPN 2014-01 - Confidential Services to Adolescents.....	35
E. FPAR: Family Planning Annual Reporting Requirement and Instructions	36
F. Title X Resources and Links.....	37
G. HHS Administrative Regulations that apply to Title X Grants and Programs	38
3. Civil Rights Act of 1964.....	39
4. Privacy Act of 1974.....	39
5. Non-Discrimination on the Basis of Disability (45 CFR Part 84)	40
6. Occupational Safety and Health Standards (29 CFR Part 1910 Subpart E)	40
7. Health Insurance Portability and Accountability Act of 1996 (HIPAA).....	41
8. Human Trafficking Laws	43
9. Patient Protection and Affordable Care Act (ACA)	45

B. Michigan Family Planning Information: Legislation, Resources and Requirements

1. Michigan Public Health Code Family Planning Authority	46
2. Appropriations	47
3. Public Health Codes.....	47
A. HIV Testing Law	47
B. Pharmacy Law	47
C. Mental Health Services	47
D. Substance Abuse	47
E. Public Act 360 of 2002	48
F. Confidentiality of Minors	48
G. Adoption	48
H. Licensing for Health Care Professionals.....	48
I. Drug Control License & Dispensing of Pharmaceuticals	48
J. Sexual Assault and Coercion Legislation & Resources.....	50
K. Child Protection and Mandated Reported Legislation.....	51
L. Michigan Human Trafficking Law & Resources.....	51

M. Expedited Partner Therapy (EPT) Legislation and Guidance.....	53
4. Additional Michigan and Medicaid Resources	
A. Zika virus information.....	54
B. Immunizations.....	54
C. HIV testing, counseling and care coordination.....	54
D. Genetics.....	54
E. Medicaid Policy, Manual and Billing information.....	54
5. Michigan Title X Family Planning Program Requirements	
A. Minimum Family Planning Program Requirements (MPRs)	55
B. MDHHS Minimum Family Planning Reporting Requirements (MRRs).....	58
C. Michigan Annual Plan Instructions	60
D. Financial Management and Audit Requirements	62

II. Administrative Program Requirements

A. Overview of Program Requirements	65
B. Eligibility, Application and Grant Process	
1. Applicability	65
2. Definitions	66
3. Eligibility.....	69
4. Application.....	70
5. Funding	71
6. Notice of Award.....	72
7. Use of Grant Funds	72
C. Project Management and Administration	
8. Project Management and Administration	72
8.1 Voluntary Participation	72
8.2 Prohibition of Abortion	73
8.3 Structure and Management	73
8.4 Charges, Billing and Collections	74
8.5 Project Personnel	77
8.6 Staff Training	78
8.7 Planning and Evaluation (Annual Plan)	80
9. Project Services and Clients	81
9.1 Priority to Low-Income Clients	81
9.2 Protecting the Dignity of the Individual	81
9.3 Non-Discrimination	81
9.4 Provision of Related Social Services	81
9.5 Referrals and Coordination	81
9.6 Provision of Family Planning Services using Written Clinical Protocols.....	81
9.7 Provision of Family Planning and Related Medical Services	81
9.8 Provision of a Broad Range of Family Planning Methods	82
9.9 Provision of Services without any Residency Requirement	82
9.10 Provision of Pregnancy Diagnosis and Counseling.....	82
9.11 Provision of Pregnancy Options Counseling.....	82
9.12 Compliance with Legislative Mandates.....	82

10. Confidentiality	82
11. Community Participation, Education and Project Promotion.....	83
12. Approval of Information and Education (I&E) Materials.....	84
D. Additional Administrative Requirements	
13.1 Facilities and Accessibility of Services (LEP/Disability Act)	87
13.2 Emergency Management	88
13.3 Standards of Conduct.....	89
13.4 Human Subjects Clearance for Research	89
13.5 Financial and Reporting Requirements.....	89
14. Additional Conditions	90
15. Closeout Requirements	90
16. Other Applicable HHS Regulations & Statutes	91

III. Clinical Services

A. Introduction	
17. Introduction.....	93
18. Service Plans and Protocols.....	93
I. Procedural Outline	94
D. Services to minors.....	94
20. Client Encounters	96
20.1 Checklist of FP and Related Preventive Health Services for Women.....	97
20.2 Checklist of FP and Related Preventive Health Services for Men.....	98
B. Family Planning Service	
21. Contraceptive Services.....	99
Broad Range Contraceptives.....	99
The Clinic Visit.....	100
Medical History for Female Clients.....	100
Medical History for Male Clients.....	101
Physical and Laboratory Assessment.....	101
Client Education and Counseling.....	102
Counseling Minor Clients.....	103
Counseling Returning Clients	103
Preventive Health Promotion and Referral.....	103
22. Preconception Health Services.....	104
Medical History for Female Clients.....	104
Medical History for Male Clients.....	104
Physical Examination for all Clients	105
Client Plan and Education	105
Referral	105
23. Achieving Pregnancy Services.....	105
Client Assessment.....	106
Client Education and Counseling	107
Education on Maximizing Fertility Awareness.....	107
Referral	108

24. Pregnancy Diagnosis and Counseling	108
Pregnancy Diagnosis Services	108
The Positive Test Visit	108
Pregnancy Options Counseling and Referrals.....	108
Negative Test Visit, Counseling and Referrals	110
25. Basic Infertility Services	110
The Clinic Visit.....	110
Basic Infertility Care for Females	111
Medical History for Females	111
Physical Exam for Females	111
Basic Infertility Care for Males.....	112
Medical History for Males.....	112
Physical Exam for Males.....	112
Infertility Counseling.....	112
Referral	112
26 Sexually Transmitted Infection Services	112
Reproductive Life Goals	113
Medical History.....	113
Physical Exam.....	113
Laboratory Testing.....	113
Treatment.....	115
Expedited Partner Therapy.....	115
Counseling	115
Referral.....	115
Mandatory reporting	115
27. Gynecologic Services	115
28. Related Preventive Health Services	
Clinical Breast Exam	116
Cervical Cytology (Pap Testing).....	116
Pelvic Examination.....	116
Mammography	116
Genital Examination for Minor Males	116
29. Quality Clinical Management	
Referrals and Follow-up.....	116
Pharmaceuticals.....	118
Medical Emergencies.....	120
Medical Records.....	120
Quality Improvement.....	122
Medical/Chart Audit Requirements.....	122

IV. Program Monitoring

A. Accreditation Visits and Site visit Reviews	125
B. Technical Assistance and Monitoring	128
C. MDHHS Financial Program Audit	128

V. MDHHS Title X Training

- A. Coordinators Meeting..... 130
- B. Michigan Annual Family Planning Update..... 130
- C. Additional Staff and Sub-recipient Agency Training..... 130
- D. National Meetings, Conferences and Training Centers..... 131
- E. Family Planning Advisory Council (FPAC) 132

Introduction

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

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

The MDHHS Title X Family Planning Program Standards and Guidelines are modeled on the Office of Population Affairs (OPA) Title X Family Planning Guidelines published in April 2014 and reflect regulatory changes issued in 2019. Those guidelines were contained in the following two documents:

1. *Program Requirements for Title X Funded Family Planning Projects*. The document, derived from the Title X statute, implementing regulations and other requirements under Title X of the Public Health Service Act, described program requirements for funded projects. In 2019, OPA finalized changes to the regulations and issued a final rule entitled “Compliance with Statutory Program Integrity Requirements,” 84 Fed. Reg. 7714 (Mar. 4, 2019). The Department of Health and Human Services (HHS) has reviewed the 2019 Rule and will propose revised regulations similar to those issued in 2000 (65 Fed. Reg. 41270), with updates to account for operational changes. <https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates>
2. *Providing Quality Family Planning Services (QFP)* was developed jointly by the Centers for Disease Control and Prevention (CDC) and OPA and published as a *CDC MMWR Recommendations and Report*. The QFP presents clinical recommendations for providing family planning services based on the best available scientific evidence. The QFP is intended for providers across all practice settings and serves as the clinical guidance for Title X projects. <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

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

SECTION I

Federal and State Legislation, Regulations And Resources

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

The Federal Title X Family Planning Program

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

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

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

The OPA Title X Family Planning Guidelines consist of two parts, 1) *Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019)* (hereafter referred to as *Title X Program Requirements*) and 2) *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* (the QFP). They were developed to guide grantees in understanding and implementing the family planning services grants program authorized by Title X of the PHS Act (42 U.S.C 300 et seq.) These documents form the basis for monitoring grantee projects under the Title X program. The *Title X Program Requirements* document is currently being revised to reflect regulations published March 4, 2019 in the Federal Register (42 CFR part 59, subpart A).

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

Title X Statute

TITLE X - POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES

SEC. 1001 [300]

(a) The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family ¹ participation in projects assisted under this subsection.

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

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

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

¹ So in law. See section 931(b) (l) 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.
- (3) 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) 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.

- (1) 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.

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

Title 42: Public Health PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a-4. AUTHORITY: 42 U.S.C. 300 through 300a-6.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted. (Issued Mar.4 2019)

§59.1 To what programs do these regulations apply?

(a) 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. Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and subrecipients, and grantees shall require and ensure that subrecipients (and the subrecipients of subrecipients) comply with the requirements contained in these regulations pursuant to their written contracts with such subrecipients.

(b) Except for §§59.4, 59.8, and 59.10, the regulations of this subpart are also applicable to the execution of contracts 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 and will be applied in accordance with the applicable statutes, procedures and regulations that generally govern Federal contracts. To this extent, the use of the terms: “grant”, “award”, “grantee”, and “subrecipient” in applicable regulations of this subpart will apply similarly to contracts, contractors and subcontractors, and the use of the term “project” or “program” will also apply to a project or program established by means of a contract.

[84 FR 7786, Mar. 4, 2019, as amended at 84 FR 14313, Apr. 10, 2019]

§59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Advanced Practice Provider means a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM).

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

Family planning means the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. These means include a broad range of acceptable and effective family planning methods and services, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility, including information about or referrals for adoption. Family planning services include preconception counseling, education, and general reproductive and fertility health care, in order to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. Family planning methods and services are never to be coercive and must always be strictly voluntary. Family planning does not include post-conception care (including obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.

Grantee means the entity that receives Federal financial assistance by means of a grant and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.

Low-income family means a family whose total income does not exceed 100% of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). The project director may find that low-income family also includes members of families whose annual 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:

(1) Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:

- (i) That it suspects the minor to be the victim of child abuse or incest; and
- (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

(2) For the purpose of considering payment for contraceptive services only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage, the project director may consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services. In making that determination, the project director must also consider other circumstances affecting her ability to pay, such as her total income. The project director may, for the purpose of considering whether the woman is from a low-income family or is eligible for a discount for contraceptive services on the schedule of discounts provided for in §59.5, consider her annual income as being reduced by the total annual out-of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs or estimate them at \$600.

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.

Program and *project* are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by, a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.

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.

Subrecipient means any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be referred to as "delegates" or "contract agencies."

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000; 84 FR 7787, Mar. 4, 2019; 84 FR 14313, Apr. 10, 2019]

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

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

[84 FR 7787, Mar. 4, 2019]

§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 family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents). Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.

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

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

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

(5) Not provide, promote, refer for, or support abortion as a method of family planning.

(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

¹Section 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."

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

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

(12) Should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:

- (i) Subrecipients and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided;
- (ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and
- (iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(14) Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records-maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).

(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 referral to other medical facilities when medically necessary, consistent with §59.14(a), and provide for the effective usage of contraceptive devices and practices.

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

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

- (i) Achieve community understanding of the objectives of the program.
- (ii) Inform the community of the availability of services; and
- (iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

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

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

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

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

(8) Except as provided in §59.14(a), 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; 84 FR 7787, Mar. 4, 2019]

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

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

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

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

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

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

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

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

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will, in the Department's judgment, best promote the purposes of statutory provisions applicable to the Title X program and ensure that no Title X funds are used where abortion is a method of family planning.

(b) Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process but shall be deemed ineligible for funding. The Department will explicitly summarize each requirement of the Title X regulations or include the Title X regulations in their entirety within the Funding Announcement and shall require each applicant to describe its plans for affirmative compliance with each requirement.

(c) If the proposal is deemed compliant with this regulation, then applicants will be subject to criteria for selection within the competitive grant review process, including:

(1) The degree to which the applicant's project plan adheres to the Title X statutory purpose and goals for 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), while meeting all of the statutory and regulatory requirements and restrictions, including that none of the funds shall be used in programs where abortion is a method of family planning.

(2) The degree to which the relative need of the applicant for Federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.

(3) The degree to which the applicant takes into account the number of patients, particularly low-income patients, to be served while also targeting areas that are more sparsely populated and/or places in which there are not adequate family planning services available.

(4) The extent to which family planning services are needed locally and the applicant proposes innovative ways to provide services to unserved or underserved communities.

(d) 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.

(e) No grant may be made for an amount equal to 100 percent for the project's estimated costs.
[65 FR 41278, July 3, 2000, as amended at 84 FR 7788, Mar. 4, 2019]

§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 75, subpart E.

[65 FR 41278, July 3, 2000, as amended at 81 FR 3009, Jan. 20, 2016]

§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 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

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

[65 FR 41278, July 3, 2000, as amended at 81 FR 3009, Jan. 20, 2016]

§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 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; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

[84 FR 7788, Mar. 4, 2019]

§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 as amended at 65 FR 49057, Aug. 10, 2000]

§59.13 Standards of compliance with prohibition on abortion.

A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.

[84 FR 7788, Mar. 4, 2019]

§59.14 Requirements and limitations with respect to post-conception activities.

(a) *Prohibition on referral for abortion.* A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.

(b) *Information about prenatal care.*

(1) Because Title X funds are intended only for family planning, once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care. The Title X provider may also choose to provide the following counseling and/or information to her:

- (i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;
- (ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);
- (iii) Referral to social services or adoption agencies; and/or
- (iv) Information about maintaining the health of the mother and unborn child during pregnancy.

(2) In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency.

(c) *Use of permitted lists or referrals to encourage abortion.*

(1) A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

(2) The list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in paragraph (b)(1)(ii) of this section may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortion.

(d) *Provision of medically necessary information.* Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not promote abortion as a method of family planning.

(e) *Examples.*

(1) A pregnant client of a Title X project requests prenatal health care services. Because the provision of such services is outside the scope of family planning supported by Title X, the client is referred for prenatal care and may be provided a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). Provision of a referral for prenatal health care is consistent with this part because prenatal care is a medically necessary service.

(2) A Title X project discovers an ectopic pregnancy in the course of conducting a physical examination of a client. Referral arrangements for emergency medical care are immediately provided. Such action complies with the requirements of paragraph (b) of this section.

(3) After receiving nondirective counseling at a Title X provider, a pregnant woman decides to have an abortion, is concerned about her safety during the procedure, and asks the Title X project to provide her with a referral to an abortion provider. The Title X project tells her that it does not refer for abortion, but provides the following: A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), which is not presented as a referral for abortion, but as a list of comprehensive primary care and prenatal care providers that does not identify which providers perform abortion, and the project staff member does not identify such providers on the list; and information about maintaining her health and the health of her unborn child during pregnancy. Such actions comply with paragraphs (a) through (c) of this section.

(4) A pregnant woman asks the Title X project to provide her with a list of abortion providers in the area. The project tells her that it does not refer for abortion and provides her a list that consists of hospitals and clinics and other providers, all of which provide comprehensive primary health care (including prenatal care), as well as abortion as a method of family planning. Although there are several licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in the area that do not provide abortion as a method of family planning, none of these providers is included on the list. Provision of the list is inconsistent with paragraphs (a) and (c) of this section.

(5) A pregnant woman requests information on abortion and asks the Title X project to refer her for an abortion. The counselor tells her that the project does not consider abortion a method of family planning and, therefore, does not refer for abortion. The counselor offers her nondirective pregnancy counseling, which may discuss abortion, but the counselor neither refers for, nor encourages, abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services and offers her the list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), assistance, and information for pregnant women described in paragraph (b) of this section. None of the providers on the list provide abortions. Such actions are consistent with paragraphs (a) through (c) of this section.

(6) Title X project staff provide contraceptive counseling to a client in order to assist her in selecting a contraceptive method. In discussing oral contraceptives, the project counselor provides the client with information contained in the patient package insert accompanying a brand of oral contraceptives, referring to abortion only in the context of a discussion of the relative safety of various contraceptive methods and in no way promoting abortion as a method of family planning. The provision of this information is consistent with paragraph (d) of this section and this section generally and does not constitute an abortion referral.

[84 FR 7788, Mar. 4, 2019]

§59.15 Maintenance of physical and financial separation.

A Title X project must be organized so that it is physically and financially separate, as determined in accordance with the review established in this section, from activities which are prohibited

under section 1008 of the Public Health Service Act and §§59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program. In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities. Mere bookkeeping separation of Title X funds from other monies is not sufficient. The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances. Factors relevant to this determination shall include:

(a) The existence of separate, accurate accounting records.

(b) The degree of separation from facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities.

(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

(d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

[84 FR 7788, Mar. 4, 2019, as amended at 84 FR 14313, Apr. 10, 2019]

§59.16 Prohibition on activities that encourage, promote, or advocate for abortion.

(a) *Prohibition on activities that encourage abortion.*

(1) A Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions in the funded project that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion for family planning purposes.

(2) Prohibited actions include the use of Title X project funds for the following:

- (i) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning.
- (ii) Providing speakers or educators who promote the use of abortion as a method of family planning.
- (iii) Attending events or conferences during which the grantee or subrecipient engages in lobbying.
- (iv) Paying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes.
- (v) Using legal action to make abortion available in any way as a method of family planning; and
- (vi) Developing or disseminating in any way materials (including printed matter, audiovisual materials, and web-based materials) advocating abortion as a method of family planning.

(b) *Examples.*

(1) Clients at a Title X project are given brochures advertising a clinic that provides abortions, or such brochures are available in any fashion at a Title X clinic (sitting on a table or available or visible within the same space where Title X services are provided). Provision or availability of the brochure violates paragraph (a)(2)(vi) of this section.

(2) A Title X project makes an appointment for a pregnant client for an abortion for family planning purposes. The Title X project has violated paragraph (a)(1) of this section.

(3) A Title X project pays dues with project funds to a State association that, among other activities, lobbies at State and local levels for the passage of legislation to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity and does not separately collect and segregate the funds for such purposes. Payment of dues to the association violates paragraph (a)(2)(iv) of this section.

(4) An organization conducts a number of activities, including operating a Title X project. The organization uses non-project funds to pay dues to an association that, among other activities, engages in lobbying to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity. Payment of dues to the association by the organization does not violate paragraph (a)(2)(iv) of this section.

(5) An organization that operates a Title X project engages in lobbying to increase the legal availability of abortion as a method of family planning. The project itself engages in no such activities, and the facilities and funds of the project are kept separate from prohibited activities. The project is not in violation of paragraph (a)(2)(i) of this section.

(6) Employees of a Title X project write their legislative representatives in support of legislation seeking to expand the legal availability of abortion, in their personal capacities and using no project funds to do so. The Title X project has not violated paragraph (a)(2)(i) of this section.

(7) On her own time and at her own expense, a Title X project employee speaks before a legislative body in support of abortion as a method of family planning. The Title X project has not violated paragraph (a)(2)(i) of this section.

(8) A Title X project uses Title X funds for sex education classes in a local high school. During the course of the class, information is distributed to students that includes abortion as a method of family planning. The Title X project has violated paragraph (a)(2)(vi) of this section.

[84 FR 7788, Mar. 4, 2019]

§59.17 Compliance with reporting requirements.

(a) Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws").

(b) A project may not receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:

(1) Has in place and implements a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:

- (i) A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client's sexual partner(s);
- (ii) Timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or provider with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws.

- (iii) Protocols to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and
 - (iv) Commitment to conduct a preliminary screening of any minor who presents with a sexually transmitted infection (STI), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STIs.
- (2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section, including which:
- (i) Indicate the age of minor clients.
 - (ii) Indicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required; and
 - (iii) Document each notification or report made pursuant to such State notification laws.
- (c) Continuation of grantee or subrecipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.
- (d) The Secretary may review records maintained by a grantee or subrecipient for the purpose of ensuring compliance with the requirements of this section, the requirement to encourage family participation in family planning decisions, or any other section of this rule.
[84 FR 7788, Mar. 4, 2019]

§59.18 Appropriate use of funds.

(a) Title X funds shall not be used to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient. Funds shall only be used for the purposes, and in direct implementation of, the funded project, expressly permitted by this regulation and authorized within section 1001 of the Public Health Service Act, that is, to offer family planning methods and services. Grantees must use the majority of grant funds to provide direct services to clients, and each grantee shall provide a detailed plan or accounting for the use of grant dollars, both in their applications for funding, and in any annually required reporting. Any significant change in the use of grant funds within the grant cycle shall not be undertaken without the approval of the Office of Population Affairs.

(b) Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for office.

(c) Each project supported under Title X shall fully account for, and justify, charges against the Title X grant. The Department shall put additional protections in place to prevent possible misuse of Title X funds through misbilling
 g or overbilling, or any other unallowable expense.

[84 FR 7788, Mar. 4, 2019]

§59.19 Transition provisions; compliance.

(a) *Compliance date concerning physical and financial separation.* The date by which covered entities must comply with the physical separation requirements contained in §59.15 is March 4, 2020. The date by which covered entities must comply with the financial separation requirements contained in §59.15 is July 2, 2019.

(b) Compliance date concerning applications. The date by which covered entities must comply with §59.7 and 59.5(a)(13) (as it applies to grant applications) is the date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.

(c) Compliance date concerning reporting, assurance, and provision of service requirements. The date by which covered entities must comply with §§59.5(a)(12), 59.5(a)(13) (as it applies to all required reports), 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18 is July 2, 2019.
[84 FR 7788, Mar. 4, 2019, as amended at 84 FR 14313, Apr. 10, 2019]

Title X Federal Program Guidelines, Guidance and Internet Resources

Program Guidelines, Tools and Documents

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

Title X Policies

Title X Statute, Regulations and Legislative Mandates:

<https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates>

Program Guidelines:

Program Requirements for Title X Funded Family Planning Projects

<https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&mc=true&node=sp42.1.59.a&rgn=div6>

Compliance with Statutory Program Integrity Requirements (2019)

<https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates-0>

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

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

The Reproductive Health National Training Center (RHNTC) provides resources, materials, and training packages to assist with compliance with Title X guidelines.

<https://rhntc.org/title-x-guidelines>

OPA Program Priorities and Key Issues

<https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/key-issues-title-x-grantees>

Sterilization of Persons in Federally Assisted Family Planning Projects Regulations

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

Family Planning Annual Reports

<https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report>

Program Priorities, Key Issues, Legislative Mandates

Key issues for Title X Grantees

While the requirements for Title X service grantees are derived from statute, regulations, and legislative mandates, there are additional key issues that represent overarching goals for the Title X program. These are determined based on priorities set by the Office of the Assistant Secretary of Health (OASH) and the Office of the Secretary (OS) of the Department of Health and Human Services (HHS). The FY2020 and FY2019 key issues are as follows:

1. Assuring innovative quality family planning and related preventive health services that lead to improved reproductive health outcomes and overall optimal health, which is defined as a state of complete physical, mental and social well-being and not merely the absence of disease. Guidance regarding the delivery of quality family planning services is spelled out in the April 25, 2014, MMWR, Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. Periodic updates have been made to this publication and are available on the Quality Family Planning page. It is expected that the core family planning services listed in the Program Description, and which also are included in the Quality Family Planning Services document referenced above, will be provided by each project.
2. Providing the tools necessary for the inclusion of substance abuse disorder screening into family planning services offered by Title X applicants.
3. Following a model that promotes optimal health outcomes for the client (physical, mental and social health) by emphasizing comprehensive primary health care services, along with family planning services preferably in the same location or through nearby referral providers.
4. Providing resources that prioritize optimal health outcomes (physical, mental, and social health) for individuals and couples with the goal of healthy relationships and stable marriages as they make decisions about preventing or achieving pregnancy.
5. Providing counseling for adolescents that encourages sexual risk avoidance by delaying the onset of sexual activity as the healthiest choice and developing tools to communicate the public health benefit and protective factors for the sexual health of adolescents found by delaying the onset of sexual activity thereby reducing the overall number of lifetime sexual partners.
6. Communicating the growing body of information for a variety of fertility awareness-based methods of family planning and providing tools for applicants to use in patient education about these methods.
7. Fostering interaction with community and faith-based organizations to develop a network for client referrals when needs outside the scope of family planning are identified.
8. Accurately collecting and reporting data, such as the Family Planning Annual Report (FPAR), for use in monitoring performance and improving family planning services.
9. Promoting the use of a standardized instrument, such as the OPA Program Review Tool, to regularly perform quality assurance and quality improvement activities with clearly defined administrative, clinical, and financial accountability for applicants and subrecipients; and
10. Increasing attention to CDC screening recommendations for chlamydia and other STIs (as well as HIV testing) that have potential long-term impact on fertility and pregnancy.

Legislative Mandates

The following legislative mandates have been part of the Title X appropriations language for a number of years. In addition, FY2019 appropriation language states that funds would be available “Provided, that amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.” Title X family planning services should include administrative, clinical, counseling, and referral services as well as training of staff 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 PHS Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities;” and
- “Notwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.”

OPA expects every Title X project will comply with applicable state laws in the proposed service area and will have project-wide monitoring and state-specific policies and procedures related to reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. These policies and procedures will include details related to:

1. Annual staff training on policies and procedures,
2. Implementation of policies,
3. Applicant monitoring throughout the project to ensure training and state-specific reporting is being followed, and
4. Maintenance of documentation concerning compliance.

These efforts will ensure clear understanding of and compliance with reporting processes, as well as permitting oversight and monitoring. In addition, any minor who presents with an STI, pregnancy, or any suspicion of abuse will be subject to preliminary screening to rule out victimization. Such screening is required for any individual who is under the age of consent in the State of the proposed service area.

Title X the National Family Planning Program

For 50 years, Title X family planning centers have provided high quality and cost-effective family planning and related preventive health services for low-income individuals. Family planning centers play a critical role ensuring access to voluntary family planning services and education to clients based on their ability to pay.

Family planning centers offer a broad range of family planning services including a broad range of FDA-approved contraceptive methods and related counseling; preconception health; infertility; achieving pregnancy; screening and treatment for sexually transmitted infections (STIs); pregnancy diagnosis; breast and cervical cancer screening; human immunodeficiency virus (HIV) counseling and testing; and other patient education and referrals.

Title X Providers

The U.S. Department of Health and Human Services' Office of Population Affairs (OPA) oversees the Title X program. OPA currently funds a network of 72 family planning services grantees which maintain thousands of service sites across the U.S. In 2019, Title X funds supported 3,825 service sites and served over 3.1 million family planning clients. Services are provided through state, county, and local health departments; community health centers; and hospital-based, school-linked, faith-based, other private nonprofit centers.

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

The Title X Mission

Title X assists individuals and couples in planning and spacing births through the provision of voluntary, confidential and low-cost education, counseling, and related comprehensive medical services. Title X family planning services contribute to positive birth outcomes and improved maternal and infant health.

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

- The Reproductive Health National Training Center (RHNTC) and the National Clinical Training Center (NCTC) provide training for family planning clinic personnel that focus on program compliance and clinical training, service delivery, management, systems improvement, coordination, strategic initiatives, quality improvement, and evaluation.
- Family planning research and evaluation to improve Title X service delivery and inform the broader reproductive health care field
- Information dissemination and community-based education and outreach

OPA Program Policy Notice Series

In June 2014, OPA initiated the Program Policy Notice (PPN) series. It replaced the OPA Program Instruction Series which was retired with the April 2014 publication of the [Program Requirements for Title X Funded Family Planning Projects](#). OPA Program Policy Notices will be issued periodically to define and/or clarify policies or procedures that grantees funded under the Title X Family Planning Program must follow. OPA Program Policy Notices are listed here most recent first:

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

Integrating with Primary Care Providers

OPA Program Policy Notice 2016-11

Release Date: November 22, 2016

I. Purpose

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

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

II. Background

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

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

Title X Program Requirements align closely with the Title X statute and family planning services project implementing regulations (42 CFR part 59, subpart A), as well as other applicable federal

statutes, regulations, and policies. This PPN is intended to help Title X grantees address integrated care settings with regard to Title X Program Requirements.

III. Clarification

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

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

Strategy

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

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

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

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

- Clients receiving only Title X family planning services with family incomes at or below 100% of the FPL must not be charged for services received. In order to comply with Title X regulations, any nominal fee typically collected by a HRSA health center program grantee or look-alike would **not be charged to the client receiving only Title X family planning services**.
- Clients receiving only Title X family planning services with family incomes that are between 101% FPL and 250% FPL must be charged in accordance with a specific Title X SFDS based on the client's ability to pay. Any differences between charges based on applying the Title X SFDS and the health center's discounting schedule could be allocated to Title X grant funds. This

allocation is aligned with the guidance provided in HRSA’s PIN 2014-02, as discussed above. This PIN states that program grantees, “*may receive or have access to other funding sources (e.g., Federal, State, local, or private funds) that contain terms and conditions for reducing patient costs for specific services. These terms and conditions may apply to patients over 200 percent of the FPG [Federal Poverty Guidelines]. In such cases, it is permissible for a health center to allocate a portion (or all) of this patient’s charge to this grant or subsidy funding source.*”ⁱⁱ

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

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

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

Issue 2: Fulfilling Data Reporting Requirements

Strategy

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

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

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

Strategy

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

payers, as long as the provider uses the appropriate SFDS. Inability to pay, however, cannot be a barrier to services.^v Providers may bill third-party payers for services that the client identifies as non-confidential.

Endnotes

ⁱ Section 8.4 of the Title X Program Requirements contains information related to charges, billing, and collections. The program requirements in section 8.4 most relevant to charging clients at or below 100% of the FPL, between 101% and 250% of the FPL, and above 250% of the FPL, are as follows:

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

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

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

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

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

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

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

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

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

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

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

Confidential Services to Adolescents

OPA Program Policy Notice 2014-01

Release Date: June 5, 2014

I. Purpose

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

II. Background

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

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

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

III. Clarification

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

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

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

FPAR: Family Planning Annual Reporting Requirements and Instructions

Family Planning Annual Report

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

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

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

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

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

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

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

<https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report>

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

<https://opa.hhs.gov/sites/default/files/2021-02/fpar-forms-instructions-reissued-jan-2021.pdf>

Title X Resources and Links

Department of Health and Human Services Websites		
<p>https://opa.hhs.gov/ (Office of Population Affairs)</p> <p>https://www.ctcfp.org/ (National Clinical Training Center for Family Planning)</p> <p>https://www.hiv.gov/ (Office of HIV/AIDS)</p> <p>https://www.hhs.gov/ohrp/ (Office of Human Research Protections)</p> <p>https://www.minorityhealth.hhs.gov/ (Office of Minority Health)</p> <p>https://www.hrsa.gov/opa/index.html (Office of Pharmacy Affairs- 340B Program)</p> <p>https://www.cdc.gov/zika/index.html (CDC Zika Virus Website)</p>	<p>https://www.hhs.gov/vaccines/index.html (National Vaccine Program Office)</p> <p>https://rhntc.org/ (Reproductive Health National Training Center)</p> <p>https://opa.hhs.gov/grant-programs/teen-pregnancy-prevention-program-tpp (Office of Teen Pregnancy Prevention)</p> <p>https://www.hhs.gov/surgeon-general/index.html (Office of the Surgeon General)</p> <p>https://www.womenshealth.gov/ (Office on Women’s Health)</p> <p>https://health.gov/our-work/pcsfm (President’s Council on Physical Fitness & Sports)</p>	<p>https://health.gov/healthypeople (Healthy People 2030)</p> <p>https://health.gov/our-work/health-literacy/resources/national-health-information-center (National Health Information Center)</p> <p>https://opa.hhs.gov/research-evaluation/opa-publications (OPA Research & Evaluation-Publications)</p> <p>https://www.osha.gov/laws-regs (OSHA Regulations)</p> <p>https://ori.hhs.gov/ (Office of Research Integrity)</p> <p>https://www.grants.gov/ (Grant Opportunities)</p>

Office of Population Affairs Publications

Providing Information and Education to the public, as well as to Title X grantees, is an important component of the Title X Program. Publications can be accessed and downloaded from the OPA website under Reproductive Health > Preventing Pregnancy > Basics of Fertility > Sexually Transmitted Infections > Reproductive Cancers > Preventing HIV > Optimal Health [Reproductive Health | HHS Office of Population Affairs](#)

Administrative Regulations that apply to Title X Grants

HHS Grants Policy Statement 2007: The Department of Health and Human Services Grants Policy Statement summarizes the general terms and conditions of HHS grant awards which apply to Title X grants. <https://www.ahrq.gov/funding/policies/hhspolicy/index.html>

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

- 2 CFR Chapter I, Chapter II, Part 200: Uniform administrative requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule. Federal Register December 26, 2013. This guidance streamlined requirements and supersedes administrative requirements (A-110 and A-102), cost principles (A-21, A-87, and A-122), audit requirements (A-50, A-89, and A-133), and HHS regulations (45 CFR Parts 74 and 92). <https://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf>
- 45 CFR Part 75: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards and is available as an electronic document: <https://www.law.cornell.edu/cfr/text/45/part-75/subpart-F>
- 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964 <https://www.law.cornell.edu/cfr/text/45/part-80>
- 45 CFR Part 81: Practice and procedure for hearings under Part 80 of this Title <https://www.law.cornell.edu/cfr/text/45/part-81>
- 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance <https://www.law.cornell.edu/cfr/text/45/part-84>
- 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance <https://www.law.cornell.edu/cfr/text/45/part-91>
- 37 CFR Part 401: Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements <https://www.law.cornell.edu/cfr/text/37/part-401>

- 42 CFR Part 50, Subpart D: Public Health Service grant appeals procedure <https://www.law.cornell.edu/cfr/text/42/part-50/subpart-D>
- 45 CFR Part 16: Procedures of the Departmental Grant Appeals Board <https://www.law.cornell.edu/cfr/text/45/part-16>
- 45 CFR Part 100: Intergovernmental Review of Department of Health and Human Services Programs and Activities <https://www.law.cornell.edu/cfr/text/45/part-100>

Civil Rights Act of 1964

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

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

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

Protections of Employees: <https://www.eeoc.gov/employers>

Laws and Guidance: <https://www.eeoc.gov/laws-guidance>

Privacy Act of 1974

The Privacy Act of 1974 establishes a code of fair information practices governing the collection, maintenance, use, and dissemination of information about individuals maintained in record systems of federal agencies. The Privacy Act prohibits the disclosure of records about an individual without the written consent of the individual, unless the disclosure is required by statutory law.

The Act also provides individuals access to and means to seek amendment to their records and sets forth agency record-keeping requirements.

The broad purpose of the Privacy Act of 1974 was to balance the government's need to collect and maintain information about individuals with the rights of individuals to be protected against unwarranted invasions of their privacy. The Act aims to protect individuals from illegal surveillance and investigation and from potential abuses presented by increased use electronic storage of personal data by means of a universal identifier – such as social security numbers. The Act focuses on four basic policy objectives:

1. To restrict disclosure of identifiable personal records.
2. To grant individuals rights of access to records maintained on them.
3. To grant individuals rights to seek amendment of records upon showing the records to be inaccurate, irrelevant, untimely, or incomplete.
4. To establish fair practices for collection, maintenance, and disclosure of personal records.

<https://www.justice.gov/opcl/privacy-act-1974>

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

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

<https://www.hhs.gov/civil-rights/for-individuals/disability/laws-guidance/index.html>

Occupational Safety and Health Standards 29 CFR Part 1910 Subpart E

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

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

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

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

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

Administrative Simplification

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

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

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

The Privacy Rule

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

<https://www.hhs.gov/hipaa/for-professionals/privacy/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.

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

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

Transactions and Code Sets Standards

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

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

To view these rules and information sheets for both sets of standards see the following link on the CMS website: <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Transactions/TransactionsOverview>

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

Employer Identifier Standard

The Health Insurance Portability & Accountability Act of 1996 (HIPAA) requires that employers have standard national numbers that identify them on standard transactions. The Employer Identification Number (EIN), issued by the Internal Revenue Service (IRS), was selected as the identifier for employers and was adopted effective July 30, 2002. For more information, see the following CMS webpage: <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Unique-Identifier/UniqueIdentifiersOverview>

National Provider Identifier Standard

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

Additional HIPAA Internet Resources

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

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

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

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

U.S. Laws and Legislation on Human Trafficking

Federal Anti-Trafficking Laws: <https://www.state.gov/international-and-domestic-law/#laws>

The Trafficking Victims Protection Act (TVPA) of 2000 is the first comprehensive federal law to address trafficking in persons. The law provides a three-pronged approach: prevention, protection, and prosecution. The TVPA was reauthorized through the Trafficking Victims

Protection Reauthorization Acts (TVPRA) of 2003, 2005, 2008, 2013 and 2017. Under U.S. federal law, “severe forms of trafficking in persons” include sex trafficking and labor trafficking:

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

The Trafficking Victims Protection Act of 2000 (TVPA) is the cornerstone of Federal human trafficking legislation; it established methods for prosecuting traffickers, preventing trafficking, and protecting victims and survivors. It established human trafficking offenses as federal crimes. It mandates restitution to victims of trafficking. It established the Office to Monitor and Combat Trafficking in Persons, which publishes a Trafficking in Persons (TIP) report each year. The TIP report describes efforts of countries to combat human trafficking. It established the Interagency Task Force to Monitor and Combat Trafficking for implementation of the TVPA. It established the T visa to protect victims and survivors and provides a path to permanent U.S. residency.

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

The Trafficking Victims Protection Reauthorization Act of 2005 (TVPRA of 2005) established programs to shelter minor survivors of human trafficking and to assist state and local law enforcement. It expanded measures to combat trafficking internationally, including sex tourism and regulating government contracts to prohibit contracts with individuals or organizations that engage in human trafficking.

The Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA of 2008) included new prevention strategies and promoted workers’ rights for people applying for work or education visas. It established systems to gather and report human trafficking data. It expanded protections under the T visa and required screening for all unaccompanied alien minors. It enhanced sanctions against traffickers, and expanded definitions of trafficking to facilitate prosecutions.

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

The Trafficking Victims Protection Reauthorization Act of 2017 (TVPRA 2017) modified criteria for evaluating how countries combat human trafficking and limits on federal grants and contracts to entities that do not combat trafficking; protects employees from placement or recruitment fees; and included multilateral development banking in activities to prevent human trafficking.

Resources:

¹The Polaris Project: <https://polarisproject.org/>

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

Patient Protection and Affordable Care Act of 2010 (ACA)

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

About the Law

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

Affordable Care Act and Preventive Health Services for Reproductive Age Women

<https://www.healthcare.gov/preventive-care-women/>

Affordable Care Act Enrollment Resources

<https://www.healthcare.gov/apply-and-enroll/how-to-apply/>

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

Michigan Public Health Laws

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

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

The philosophy of the MDHHS Family Planning Program, consistent with that of Title X. Family Planning, is a preventive health measure which positively impacts on the health and well-being of individuals 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 clients to make well-informed reproductive health choices. MDHHS funded family planning clinics are specifically created to address the unmet family planning needs of those below poverty, and 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 no request 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\(iliqdxmzjt4wjg45giwls0j2\)\)/mileg.aspx?page=AppropriationBillsPassed](http://www.legislature.mi.gov/(S(iliqdxmzjt4wjg45giwls0j2))/mileg.aspx?page=AppropriationBillsPassed)

Public Health Codes

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

Full Text:

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

HIV Testing Law:

[http://www.legislature.mi.gov/\(S\(tianbh3zjgkprzqwh1lusnl\)\)/mileg.aspx?page=GetObject&objectName=mcl-368-1978-5-51](http://www.legislature.mi.gov/(S(tianbh3zjgkprzqwh1lusnl))/mileg.aspx?page=GetObject&objectName=mcl-368-1978-5-51)

Michigan HIV & STD Law Update Summary:

https://www.michigan.gov/documents/mdhhs/Michigan_HIV_STD_Law_Updates_FAQ_650285_7.pdf

Pharmacy Law:

[http://www.legislature.mi.gov/\(S\(5x5gcu3ujstowyqx4jnscoxx\)\)/mileg.aspx?page=getObject&objectName=mcl-333-17745](http://www.legislature.mi.gov/(S(5x5gcu3ujstowyqx4jnscoxx))/mileg.aspx?page=getObject&objectName=mcl-333-17745)

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

Mental Health Services:

[http://www.legislature.mi.gov/\(S\(a1u31onkc2j2o5iupuptztyk\)\)/mileg.aspx?page=GetMCLDocument&objectName=Mcl-Act-258-of-1974&queryid=12811010&highlight=mental%20health%20services](http://www.legislature.mi.gov/(S(a1u31onkc2j2o5iupuptztyk))/mileg.aspx?page=GetMCLDocument&objectName=Mcl-Act-258-of-1974&queryid=12811010&highlight=mental%20health%20services)

Substance Abuse:

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

PA 360 of 2002:

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

Confidentiality of Minors:

<https://www.networkforphl.org/wp-content/uploads/2020/05/Issue-Brief-Michigan-Minor-Privacy-Laws-May-2020-Update-DC.pdf>

<https://www.umhs-adolescenthealth.org/wp-content/uploads/2019/05/confidentiality-laws-mi-spark-handout.pdf>

Adoption:

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

<https://www.mare.org/For-Families/New-to-Adoption/Find-a-Licensed-Agency>

Licensing for Health Care Professionals:

<https://www.michigan.gov/lara/0,4601,7-154-89512---,00.html>

Drug Control License & Dispensing of Pharmaceuticals

333.17745 Drug control license; patient's chart or clinical record to include record of drugs dispensed; delegating authority to dispense drugs; storage of drugs; container; label; complimentary starter dose drug; information; compliance with MCL 333.7303a; inspection of locations; limitation on delegation; receipt of complimentary starter dose drugs by pharmacist; "complimentary starter dose" defined. Sec. 17745.

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

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

(3) A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber or indirectly under his or her delegatory authority. If prescription drugs are dispensed under the prescriber's delegatory authority, the delegatee who dispenses the prescription drugs shall initial the patient's chart, clinical record, or log of prescription drugs dispensed. In a patient's chart or clinical record, a dispensing prescriber shall distinguish between prescription drugs dispensed to the patient, prescription drugs prescribed for the patient, prescription drugs dispensed or prescribed for expedited partner therapy as authorized in section 5110, and prescription drugs dispensed or prescribed as authorized under section 17744a or 17744b. A dispensing prescriber shall retain information required

under this subsection for not less than 5 years after the information is entered in the patient's chart or clinical record.

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

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

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

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

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

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

(c) The date the prescription drug was dispensed.

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

(e) The directions for use.

(f) The name and strength of the prescription drug.

(g) The quantity dispensed.

(h) The expiration date of the prescription drug or the statement required under section 17756.

(8) A dispensing prescriber who dispenses a complimentary starter dose drug to a patient, or an advanced practice registered nurse as that term is defined in section 17201 who dispenses a complimentary starter dose drug to a patient under section 17212, shall give the patient the information required in this subsection, by dispensing the complimentary starter dose drug to the patient in a container that bears a label containing the required information or by giving the patient a written document that may include, but is not limited to, a preprinted insert that comes with the complimentary starter dose drug and that contains the required information. The information required to be given to the patient under this subsection includes all of the following:

(a) The name and strength of the complimentary starter dose drug.

(b) Directions for the patient's use of the complimentary starter dose drug.

(c) The expiration date of the complimentary starter dose drug or the statement required under section 17756.

(9) The information required under subsection (8) is in addition to, and does not supersede or modify, other state or federal law regulating the labeling of prescription drugs.

(10) In addition to meeting the requirements of this part, a dispensing prescriber who dispenses controlled substances shall comply with section 7303a.

(11) The board may periodically inspect locations from which prescription drugs are dispensed.

(12) The act, task, or function of dispensing prescription drugs shall be delegated only as provided in this part and sections 16215, 17048, 17211a, 17212, and 17548.

(13) A supervising physician may delegate in writing to a pharmacist practicing in a hospital pharmacy within a hospital licensed under article 17 the receipt of complimentary starter dose drugs other than controlled substances as defined in article 7 or federal law. When the delegated receipt of complimentary starter dose drugs occurs, both the pharmacist's name and the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each receipt. A pharmacist described in this subsection

may dispense a prescription for complimentary starter dose drugs written or transmitted by facsimile, electronic transmission, or other means of communication by a prescriber.

(14) As used in this section, "complimentary starter dose" means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients.

History: 1978, Act 368, Eff. Sept. 30, 1978 ;-- Am. 1980, Act 431, Eff. Mar. 31, 1981 ;-- Am. 1986, Act 304, Eff. Mar. 31, 1987 ;-- Am. 1990, Act 333, Eff. Mar. 28, 1991 ;-- Am. 1992, Act 281, Imd. Eff. Dec. 18, 1992 ;-- Am. 1993, Act 305, Imd. Eff. Dec. 28, 1993 ;-- Am. 1996, Act 355, Imd. Eff. July 1, 1996 ;-- Am. 1997, Act 186, Eff. Mar. 31, 1998 ;-- Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007 ;-- Am. 2011, Act 210, Imd. Eff. Nov. 8, 2011 ;-- Am. 2013, Act 186, Eff. Mar. 14, 2014 ;-- Am. 2014, Act 311, Imd. Eff. Oct. 14, 2014 ;-- Am. 2014, Act 525, Imd. Eff. Jan. 14, 2015 ;-- Am. 2016, Act 379, Eff. Mar. 22, 2017 ;-- Am. 2016, Act 499, Eff. Apr. 9, 2017

Popular Name: Act 368

Sexual Assault and Coercion Legislation

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

In Michigan, the law regarding sexual assault is called the Criminal Sexual Conduct Act. It is gender neutral and includes marital, stranger, date, acquaintance, and child sexual assault. For a description and summary see: <https://www.michigan.gov/datingviolence/0,4559,7-233-46552-169748--,00.html>

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

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

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

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

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

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

Domestic and Sexual violence Professional Training and Resources

https://www.michigan.gov/mdhhs/0,5885,7-339-71548_7261_18139---,00.html

Michigan Sexual Assault Hotline: 1-855-VOICES4 (864-2374)

Child Protection & Mandated Reporting Legislation

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

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

The following links provide further assistance:

MDHHS Mandated Reporters Page

https://www.michigan.gov/mdhhs/0,5885,7-339-73971_7119_50648_44443---,00.html

Michigan Child Protection Law (Act 238 Of 1975)

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

Michigan Human Trafficking Law

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

The human trafficking law was again overhauled in 2014 with a series of 21 bills that include safe harbor provisions for victims and stronger punishments for traffickers, including lengthening the statute of limitations on these crimes and made the trafficking of a child an offense that must be reported by mandatory reporters. It created a standing Human Trafficking Commission within the Department of Attorney General and a Human Trafficking Health Advisory Board within the Department of Health and Human Services. Most of the new legislation took effect on January 14, 2015.

[http://www.legislature.mi.gov/\(S\(0hbxyzb4zs5on2zljgwm3urh\)\)/mileg.aspx?page=GetObject&objectname=mcl-750-462a](http://www.legislature.mi.gov/(S(0hbxyzb4zs5on2zljgwm3urh))/mileg.aspx?page=GetObject&objectname=mcl-750-462a)

Michigan law prohibits:

1. Forced labor or services by force, fraud, or coercion

- a. Force includes, but is not limited to, physical violence, threat of physical violence or actual physical restraint or confinement or threat of actual physical restraint of confinement, without regard to whether injury occurs.
- b. Fraud includes, but is not limited to, a false or deceptive offer of employment or marriage.
- c. Coercion includes but is not limited to:
 - i. Threatening to harm or physically restrain any individual or the creation of a scheme, plan, or pattern to make a person believe that any act would result in psychological, reputational, financial harm, or physical restraint.
 - ii. Abusing or threatening abuse of the legal system, such as threatening arrest or deportation.
 - iii. Knowingly destroying, concealing, removing, confiscating any passport, other immigration documents, or government identification.
- 2. Debt Bondage
- 3. Enterprise Liability; Financially Benefitting
- 4. Trafficking a Minor
 - a. Covers both sex trafficking and labor trafficking of a minor
 - b. No Force, Fraud or Coercion required in the case of minors
 - c. Regardless of whether the person knows the age of the minor

Safe Harbor - Safe harbor provisions in the 2014 Michigan human trafficking legislation:

- 1. 2014 PA 336 provides safe harbor to minor sex trafficking victims by presuming that a minor found engaging in prostitution is a victim of human trafficking and mandates law enforcement to refer the minor victims for appropriate treatment within MDHHS.
- 2. 2014 PA 342 provides safe harbor to minor sex trafficking victims by establishing probate court jurisdiction for minor human trafficking victims who are dependent and in danger of substantial harm.
- 3. 2014 PA 335 provides safe harbor by allowing victims of human trafficking to clear their criminal record of crimes they were forced to commit by their traffickers.
- 4. 2014 PA 334 provides adult human trafficking victims safe harbor through a diversion process to avoid prostitution convictions.

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

- 1. Increases the crime of buying sex from a minor to a felony.
- 2. Overhauls the human trafficking portion of the penal code in line with the 2014 human trafficking provisions.
- 3. Removes the statute of limitations in cases where trafficking is punishable by life and otherwise lengthened the statute of limitations for bringing charges against traffickers.

4. Strengthens penalties against sex-buyers (johns) by revising the definition of Sex Offender to include the new crime of soliciting prostitution from a minor and includes those engaging in trafficking minors for sex; and requires johns to be placed on sex offender registry.
5. Removes outdated gender-specific references regarding prostitution and increases fines for operating a place of prostitution.
6. Updates the Crime Victim's Rights Act to account for the 2014 human trafficking laws.
7. Makes human trafficking of a child an offense that must be reported by mandatory reporters to Child Protective Services.
8. Reflects changes in the sentencing guidelines for increased penalties against criminals soliciting sex from minors under 16 years of age.

Michigan Human Trafficking Resources:

<https://humantraffickinghotline.org/state/michigan>

MDHHS Human Trafficking of Children Protocol:

https://www.michigan.gov/documents/dhs/HumanTraffickingProtocol_440356_7.pdf

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

Fact Sheet on Human Trafficking:

https://www.acf.hhs.gov/sites/default/files/documents/otip/fact_sheet_human_trafficking_fy18.pdf
https://www.acf.hhs.gov/sites/default/files/documents/otip/fact_sheet_human_trafficking_fy18.pdf

Expedited Partner Therapy Legislation

Public Act 525 of 2014 (MCL 333.5110) authorized the use of expedited partner therapy (EPT) in Michigan for certain sexually transmitted infections as designated by MDHHS. In January 2015, chlamydia and gonorrhea were designated as appropriate for the use of EPT.

[http://www.legislature.mi.gov/\(S\(nj1cpiiegpl0cokontzv2ooxv\)\)/documents/mcl/pdf/mcl-333-5110.pdf](http://www.legislature.mi.gov/(S(nj1cpiiegpl0cokontzv2ooxv))/documents/mcl/pdf/mcl-333-5110.pdf)

MDHHS developed the following document to provide guidance for health care providers using EPT:

https://www.michigan.gov//documents/mdch/EPT_for_Chlamydia_and_Gonorrhea_-_Guidance_for_Health_Care_Providers_494241_7.pdf

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

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

Following CDC guidance in response to the COVID-19 emergency, MDHHS temporarily expanded recommendations for EPT as of April 2020. [Dr. J Letter STD Options 4-15-2020.pdf](#)

Additional Michigan Resources

Zika virus resources:

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

Immunizations:

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

HIV Testing Counseling and Referral Services:

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

Genetics:

<https://migrc.org/>

Michigan Medicaid Policy Information:

Links to the Medicaid Provider Manual and Medicaid Policy Bulletins.

https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42553-188444--_00.html

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

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

Medicaid Billing and Reimbursement Information:

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

https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_42542_42543_42546_42551-159815--_00.html

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

MDHHS Family Planning Minimum Program Requirements (MPRs)

Note: The MDHHS Family Planning Minimum Program Requirements (MPRs) are currently under revision for Cycle 8 of the Michigan Local Public Health Accreditation Program. Updated MPRs are pending approval by the Michigan Local Public Health Accreditation Commission. Updated Family Planning MPRs will reflect the 2019 Title X Final Rule and Revised 42 CFR Part 59 published May 4, 2019.

ELEMENT DEFINITION:

Family Planning services offer comprehensive preventive reproductive health care that includes general health assessment and examination; routine screening for sexually transmitted infections, 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 §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 §59.5 (a)(2).
3. Provide services in a manner which protects the dignity of the individual. **Reference:** 42 CFR CH. 1 §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 §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 §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 §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 §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 §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 §59.5 (a)(9).
10. Provide for an advisory committee. **Reference:** 42 CFR CH. 1 §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 §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 §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 §59.5 (b)(3).
14. Provide for orientation and in-service training for all project personnel. **Reference:** 42 CFR CH.1 §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 §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 §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 §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 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 §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 §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 §59.9.

These Minimum Program Requirements (MPR's) are used as indicators for the MDHHS accreditation/site review process. They are based on the Title X Statute, 42 CFR PART 59, Office of Population Affairs (OPA) Program Requirements and the MDHHS Title X Family Planning Program Standards and Guidelines. The Family Planning Indicator tool can be found on the Michigan Local Public Health Accreditation website: <https://accreditation.localhealth.net/> and on the MDHHS Family Planning website at: <https://www.michigan.gov/familyplanning>.

Michigan Department of Health and Human Services

Minimum Reporting Requirements (MRRs)

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

These documents include the:

- The Family Planning Annual Report (FPAR)
 - Mid-Year FPAR Report
 - Year-End FPAR Report
- Family Planning Annual Health Care Plan:
 - Needs Assessment & Health Care Plan Narrative
 - Work Plan

These reports must be submitted accurately and timely. The information is used for essential activities including legislative reporting, federal reporting requirements for the State, budgeting, funding allocations, and other aspects of financial management. In addition, this data provides statistical information needed for program evaluation, assessment of need, and other activities required of Title X Family Planning Projects.

For calendar year 2019, MDHHS is using a Michigan-specific worksheet to collect race and ethnicity specific data for the federal FPAR tables 1-5, 7,8, and 11. The worksheets will automatically populate the standard federal FPAR tables. This data will assist MDHHS and sub-recipients to identify and analyze any disparities in services among racial and ethnic groups and address them to improve the health of Michigan communities.

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

Local Public Health Departments must also submit Medicaid Cost-Based Reimbursement Tracking Information through EGrAMS with the year-end final status report.

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

Michigan Title X Family Planning

Annual Health Care Plan Guidance

FY 2020

The Annual Health Care Plan highlights a family planning agency’s program accomplishments and challenges throughout the current fiscal year, in addition to outlining service delivery plans for the next fiscal year. This document provides guidance on the submission requirements for the Annual Health Care Plan narrative and associated appendices.

I. Program Description

- A. Highlight significant program achievements, milestones, or other notable accomplishments during this past fiscal year.
- B. Highlight program and community changes (e.g., staffing or administrative changes, supply issues, local policy/community issues, or provider relationships) that occurred this past fiscal year, focusing on service delivery and priority population(s) affects, and potential solutions.

II. Priority Population(s) and Target Service Area(s)

- A. Provide a brief description of the agency’s priority population(s) and target service area(s).

Insert the below table into this narrative section and indicate the projected number of unduplicated users during calendar year 2020 for each table row. For demographic categories, refer to FPAR Table 1. For income level, refer to FPAR Table 4.

Demographic Category	Unduplicate d Users 2020
Males	
Females	
Teens	
Income Level	Unduplicated Users 2020
At or below 100% of poverty	
Above 100% but no more than 150%	
Above 150% but not more than 200%	
Above 200% but not more than 250% of poverty	
Above 250% of poverty	

III. Agency Capacity & Staffing Structure

- A. Provide a copy of the agency’s current family planning organizational chart, including staff names, positions, and FTEs. Submit this document as an attachment.

- B. Identify and report all services to be provided to clients under Title X by completing the *Family Planning Services Provided* worksheet (See [Family Planning website](#), 'Information for Providers').
 - C. Include the agency's current *Fee Schedule*. Submit this document as an attachment.
 - D. Submit the agency's coordinator information, main office hours, agency clinic location(s), and clinic hours of operation on the *Family Planning Agency Clinic Location(s) & Schedule(s)* template (See [Family Planning website](#), 'Information for Providers').
- IV. Program Work Plan
- A. Provide a brief progress report on the previous year's goals, objectives, and activities using the *Family Planning Work Plan Progress Report* (See [Family Planning website](#), 'Information for Providers'), including community education and promotion activities.
 - B. Develop project goals and objectives for next fiscal year that are specific, measurable, attainable, realistic, and time bound (S.M.A.R.T.), and address Title X priorities. Goals and objectives should reflect regional needs and engage priority populations. Submit on the required work plan format, *Family Planning Work Plan* (See [Family Planning website](#), 'Information for Providers') as an attachment.
 - i. Include at least one project goal and objective for Community Education Activities (See Section 11.2 of the *Michigan Title X Family Planning Program Standards and Guidelines Manual*).
 - ii. Include at least one project goal and objective for Community Promotion Activities (See Section 11.3 of the *Michigan Title X Family Planning Program Standards and Guidelines Manual*).
- V. Family Planning Advisory Council (See Section 11.1 of the *Michigan Title X Family Planning Program Standards and Guidelines Manual*).
- A. Provide a brief description of the Advisory Council's purpose.
 - B. Include the following Advisory Council documents as attachments: next fiscal year's meeting schedule, member roster, and minutes from the last held Council meeting.
- VI. Information and Education (I&E) Committee (See Sections 12.1 thru 12.4 of the *Michigan Title X Family Planning Program Standards and Guidelines Manual*).
- A. Provide a brief description of the I&E Committee's function.
 - B. Include the current fiscal year's meeting schedule and the member roster as an attachment. The roster should indicate what community populations/groups the member represents (e.g., agency or professional organization name, or teen, male, client, or parent).

- C. Provide a brief description of how the member composition of the I&E Committee represents the population served in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age.
 - D. Describe the process the I&E Committee will use to review and track previously approved materials. Previously approved materials must be reviewed every three years to ensure information is still relevant, factually accurate, and appealing to its target audience.
- VII. Electronic Health Records/Electronic Medical Record (EHR/EMR)
- A. Provide the name and version of your EHR/EMR system along with the following details:
 - i. Does your medical director utilize the EHR/EMR during the quality assurance process?
 - ii. Do you currently utilize your EHR/EMR to manage program inventory?
- VIII. Chlamydia Screening
- A. Please describe your agency's Chlamydia screening practices for all core units of service under Title X.

Financial Management Audit Requirements

Financial Management Audit Requirements

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

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

1. Required Audit or Exemption Notice

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

A. Single Audit

Grantees that are a state, local government or non-profit organization that expend \$750,000 or more in federal awards during the Grantee's fiscal year must submit a Single Audit to the Department, regardless of the amount of funding received from the Department. The Single Audit must comply with the requirements of the Single Audit Act Amendments of 1996, and Title 2 Code of Federal Regulations, Subpart F.

B. Audit Exemption Notice

Grantees exempt from Single Audit must submit an Audit Exemption Notice that certifies the exemption. The template Audit Exemption Notice and further instructions are available at https://www.michigan.gov/mdhhs/0,5885,7-339-73970_43164---,00.html.

2. Other Audits

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

3. Due Date and Where to Send

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

4. Penalty

A. Delinquent Single Audit

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

B. Delinquent Audit Exemption Notice

Failure to submit the Audit Exemption Notice, 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 Exemption Notice is received.

5. Management Decision

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

SECTION II

Administrative Program Requirements for Title X Family Planning Projects

A. Overview of Title X Program Requirements

The MDHHS Title X Family Planning Program requirements are modeled on the OPA Title X Family Planning Guidelines published in April 2014 consisting of the two documents below and reflect regulatory changes issued in 2019. The guidelines were contained in the following two documents:

1. *Program Requirements for Title X Funded Family Planning Projects*. The document was derived from the Title X statute, implementing regulations, and other requirements under Title X of the Public Health Service Act. In 2019, OPA finalized changes to the regulations and issued a final rule entitled “Compliance with Statutory Program Integrity Requirements,” 84 Fed. Reg. 7714 (Mar. 4, 2019). The Department of Health and Human Services (HHS) has reviewed the 2019 Rule and will propose revised regulations similar to those issued in 2000 (65 Fed. Reg. 41270), with updates to account for operational changes. <https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates>
2. *Providing Quality Family Planning Services (QFP)* was developed jointly by the Centers for Disease Control and Prevention (CDC) and OPA and published as a *CDC MMWR Recommendations and Reports*. The QFP presents clinical recommendations for providing family planning services consistent with the best available scientific evidence. The QFP is intended for providers across all practice settings and serves as the clinical guidance for Title X projects. <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

The Administrative Program Requirements section of the MDHHS Title X Family Planning Standards and Guidelines Manual, 2021 focus on the requirements outlined in the Program Requirements for Title X Funded Family Planning Projects and the 2019 “Compliance with Statutory Program Integrity Requirements”. The Clinical Services section follows the outline and recommendations in the QFP and current national standards of care to define clinical requirements for MDHHS Family Planning programs.

B. Eligibility, Application and Grant Process

1. APPLICABILITY

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

2. DEFINITIONS

Terms used throughout this document include:

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

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

<p>Family Planning Encounter</p>	<p>A family planning encounter is a documented contact between an individual and a family planning provider that is either face-to-face in a Title X service site or virtual using telehealth technology. * The purpose of a family planning encounter 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 services provided during the family planning encounter must be documented in the client record. There are two types of family planning encounters: (1) family planning encounters with a Clinical Services Provider and (2) family planning encounters with an Other Services Provider. (Title X FPAR Forms & Instructions, 2021, page 7,8)</p>
<p>Family Planning Provider</p>	<p>The term family planning provider refers to any staff member involved in providing family planning services to a client; includes physicians, physician assistants, nurse practitioners, nurse-midwives, nursing staff and other staff providing client services. (QFP page 4). For purposes of FPAR, Clinical Services Providers include physicians, physician assistants, nurse practitioners, and certified nurse midwives; and Other Services Providers include licensed nurses, nurse assistants, laboratory assistants, health educators, social workers, or clinic aids providing family planning services. (Title X FPAR Forms & Instructions, 2021, page 7)</p>
<p>Family Planning Service Site</p>	<p>The term service site refers to clinics or other locations where Title X family planning services are provided by the grantee or sub-recipient. (Title X FPAR Forms & Instructions, 2021, page 8)</p>
<p>Family Planning Client or User</p>	<p>The term family planning client refers to an individual of reproductive age who needs family planning and related preventive health services. (QFP, page 2) For purposes of FPAR, a family planning user is an individual who has at least one family planning encounter at a Title X family planning service site during the reporting period. (Title X FPAR Forms & Instructions, 2021, page 7)</p>
<p>MCIR</p>	<p>The Michigan Care Improvement Registry (MCIR) is Michigan’s online immunization registry.</p>

Risk Assessment	The term Risk Assessment as used in this document, means an objective identification of risk behaviors and situations that may lead to recognized adverse health conditions. Risk assessment leads to screening recommendations, appropriate interventions, or
Screening	The term Screening , as used in this document, means testing to identify an unrecognized disease or health condition to enable early intervention and management. Screening initiatives help lead to earlier diagnosis to reduce mortality and suffering from diseases.

* Following guidance from CDC, Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA), OPA issued communications to allow virtual encounters in Title X projects in response to the COVID-19 public health emergency. FPAR instructions issued in 2021 define a virtual family planning encounter as using telecommunications and information technology to provide access to Title X family planning and related preventive health services, including assessment, diagnosis, intervention, consultation, education and counseling, and supervision, at a distance. Telehealth technologies include telephone, facsimile machines, electronic mail systems, videoconferencing, store-and-forward imaging, streaming media, remote monitoring devices, and terrestrial and wireless communications. MDHHS notified sub-recipients of the OPA communication on April 1, 2020. [COVID Emergency - Telemedicine in the Family Planning ProgramFP-06-20.pdf](#)

3. ELIGIBILITY

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

- A. Eligible applicants **must** demonstrate past experience delivering primary care, adolescent health, reproductive health or family planning services. Potential applicants include:
 - 1. Public and private non-profit health agencies
 - 2. Local health departments
 - 3. Community health centers
 - 4. Federally Qualified Health Centers
 - 5. Rural and Urban Health Centers
 - 6. Tribal Indian health centers
 - 7. Faith based organizations

- B. Entities **must** furnish evidence of non-profit status in accordance with instructions accompanying the project grant application.

- C. Applicants **must** have providers who are or can become Medicaid enrolled providers as well as bill private third-party payers.

- D. Eligible applicants providing services beyond the Title X family planning program **must** ensure that Title X funds will be expended solely for the Title X program under the terms and conditions of the grant.
- E. Eligible applicants **must** demonstrate and assure ability to meet program requirements set forth by the Title X statute, OPA Title X regulations and MDHHS Family Planning Minimum Program Requirements.
- F. Applicants **must** have the capacity to provide a broad range of family planning methods. Grants cannot be made to entities that propose to offer only a single method or unduly limited number of family planning methods. An organization offering a single or limited number of family planning methods may receive Title X assistance only by participating as a special service with a formal agreement in place with a project offering a broad range of family planning services.
- G. The organization **must** have a governing board that is representative of the community or have a program specific family planning advisory council representative of the community.
- H. Local health departments have the primary responsibility to meet the health needs of vulnerable populations but may elect not to provide family planning services directly. (Public Health Code, 2000: Section 333.2473).
- I. Pursuant to PA 360 (2002) Section 333.1091, MDHHS **must** give priority in the allocation of funds within a service area where there are competing qualified applicants to qualified entities that do not engage in performing elective abortions within a facility owned or operated by the entity; do not maintain a policy that considers elective abortion part of a continuum of family planning or reproductive health services; and/or is not affiliated with another entity that engages in providing abortion services. (Section I, page 48)

4. APPLICATION

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

Annually, agencies awarded Title X funding in the competitive bid process **must** apply for continuing grantee sub-recipient status which includes a needs assessment and an annual

health care plan. These annual plans **must** be submitted to MDHHS and follow the guidance provided by MDHHS (See the Michigan Family Planning Information in Section I of this document for details). Technical assistance is available. The plan **must not** include activities that cannot be funded under Title X, such as abortion or lobbying activities.

5. FUNDING

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

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

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

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

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

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

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

6. NOTICE OF AWARD

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

7. USE OF GRANT FUNDS

All funds granted for Title X family planning services projects **must** be expended only for the purpose for which the funds were awarded and in accordance with the approved application and budget. Funds may not be used for prohibited activities, such as providing, referring or promoting abortion as a method of family planning, or lobbying. Funds **must** be used in accordance with the Title X family planning services projects regulations, MDHHS annual contract, and HHS grants administration regulations. HHS grants administration regulations can be accessed in the HHS Grants Policy Statement, 2007 (Section I, page 38).

C. Project Management and Administration

8. PROJECT MANAGEMENT AND ADMINISTRATION

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

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

8.1 Voluntary Participation

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

- A. Clients **must not** be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5 (a) (2)).
- B. A client's acceptance of family planning services **must not** be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or sub-recipient (Section 1007, PHS Act; 42 CFR 59.5 (a)(2)).

- C. Personnel working within the family planning project **must** be informed that they may be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).
- D. Sub-recipients **must** assure in their general consent for services that family planning services are provided on a voluntary basis, without coercion to accept services or any particular method of family planning and without prerequisite to accept any other service.

8.2 Prohibition of Abortion

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

- A. Sub-recipients **must** have written policies that clearly indicate that no Title X funds will be used in programs where abortion is a method of family planning.
- B. Additional guidance on this topic can be found in the March 4, 2019 U.S. Department of Health and Human Services published final rule, [Federal Register](#), sections 42 CFR 59.13 through 42 CFR 59.16. (Section I, pages 14-26).

8.3 Structure and Management

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

- 8.3.1 As the grantee, MDHHS **must** have a written contract with each sub-recipient and **must** maintain and provide updated MDHHS Title X Family Planning Standards and Guidelines Manual for sub-recipient agencies consistent with Title X Program Requirements and other applicable requirements (45 CFR parts 74 and 92).

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

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

- 8.3.2 Where a sub-recipient wishes to subcontract any of its responsibilities or services, a written agreement that is consistent with Title X Program Requirements **must** be in

place and **must** be approved by MDHHS. Sub-recipients **must** identify subcontracted responsibilities or services in their annual plan (45CFR parts 74 and 92).

- 8.3.3 All services purchased for project participants **must** be authorized by the project director or his/her designee on the project staff (42 CFR 59.5(b) (7)).
- 8.3.4 Where required services are provided by referral, the sub-recipient **must** have written agreements for the provision of services and reimbursement of costs as appropriate. Services provided through a contract/arrangement **must** be paid for under agreements that include a reasonable schedule of rates. (42 CFR 59.5(b) (9)).
- 8.3.5 Sub-recipients **must** be given an opportunity to participate in the establishment of MDHHS policies and guidelines (42 CFR 59.5 (a) (10)).
- 8.3.6. Sub-recipients **must** maintain a financial management system that meets Federal standards, as applicable, requirements in the contract, and which complies with Federal standards that support effective control and accountability of funds. Documentation and records of all income and expenditures **must** be maintained. (2 CFR Part 200)
- 8.3.7. Sub-recipients **must** adhere to MDHHS Title X reporting requirements (MRR). (Section I, pages 58,59)
 - A. Mid-Year and Year-End Family Planning Annual Report (FPAR)
 - B. Family Planning Needs Assessment and Health Care Plan (Annual Plan)
 - C. Sub-recipients **must** have written policies and procedures for mandatory reporting of child abuse and neglect, sexual abuse, as well as compliance with human trafficking laws.

8.4 Charges, Billing, and Collections

The sub-recipient **must** have written policies and procedures for charging, billing, and collecting funds for the services provided by the project that meet Title X requirements:

Clients **must not** be denied services or be subjected to any variation in quality of services because of inability to pay.

Sub-recipients **must** develop a schedule of discounts (sliding fee scale) to assure that clients are charged based on ability to pay (42 CFR 59.5(a) (8)). Ability to pay is determined by assessing family income using the most current Federal Poverty Level (FPL) guidelines.

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

- B. Projects must rely on client self-report when assessing client income directly. However, Title X regulations allow grantees discretion to use income verification data provided by clients because of participation in other programs operated by the organization. Projects that have access to income verification data because of a client's participation in another program may use that data rather than rely solely on client self-report.
 - C. MDHHS policy requires that the schedule of discounts **must** be developed with sufficient proportional increments to assure services are billed based on ability to pay. Sub-recipients must use the mandated quartile proportional increments that MDHHS distributes each year in developing their schedule of discounts. Sub-recipients may request and must receive an MDHHS approved waiver to use other proportional increments.
- 8.4.1 Clients whose documented income is at or below 100% of FPL **must not** be charged, although projects **must** bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).
- 8.4.2 Clients whose family income falls between 101% and 250% of the FPL **must** be charged based on the schedule of discounts developed to assure that services are billed based on ability to pay (42 CFR 59.5(a) (8)).
- 8.4.3 Fees **must** be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2). Approval of waived fees for good cause **must** be documented in the client record.
- A. Sub-recipients may opt to consider employer-sponsored health insurance denial of contraceptive coverage as a "good cause" factor in approving waived or reduced fees for contraceptive services. While employed-sponsored contraceptive coverage may be used as a factor, other circumstances such as household income **must** also be considered. Upon site manager approval, the client's household income may be adjusted by deducting the total annual out-of-pocket cost of contraceptive services (or use of \$600 as a proxy) to determine the client's place on the sliding fee scale, or to determine if fees should be waived for good cause. Sub-recipients who opt to implement contraceptive coverage as a good cause factor **must** include the process it in the agency's financial policies.
- 8.4.4 Clients whose family income exceeds 250% of the FPL **must** be charged based on a fee schedule designed to recover the reasonable cost of providing services (42 CFR 59.5(a) (8)). Sub-recipients **must** document their process for developing the fee schedule to indicate how they determined reasonable costs to be recovered. The documented process **must** include an analysis of the costs of providing services and identification of

other factors used to determine the fee schedule. Sub-recipients may elect to set their fee schedule below what would recover the actual cost of providing services, based on their specific community needs and circumstances. Sub-recipients **must** review their program costs and reassess their fee schedule at least every two years and are encouraged to do so annually. Sub-recipients **must** use the cost analysis tool developed by MDHHS Family Planning Program, unless they request and receive a waiver to use another methodology to assess program costs.

- 8.4.5 Eligibility for discounts for minors who receive confidential services **must** be based on the income of the minor (42 CFR 59.2).
- A. Unemancipated minors receiving confidential services **must** receive all required counseling for minors unless there is documentation of suspicion of child abuse or neglect and appropriate reporting. (42 CFR 59.2 (1) (i)-(ii))
 - B. Sub-recipients **must not** have a policy of no fees or flat fees for the provision of services to minors and **must not** have a fee schedule for minors that are different from the fee schedule for other populations receiving family planning services.
- 8.4.6 Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts **must** be made to obtain third party payment without the application of any discounts (42 CFR 59.5(a)(9)).
- A. With regard to insured clients, family income **must** be considered before determining whether copayments or additional fees are charged. Clients whose family income is at or below 250% FPL **must not** pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.
- 8.4.7 Where reimbursement is available from Title XIX or Title XX of the Social Security Act, a written agreement or registration with the Title XIX or the Title XX state agency at either the grantee or sub-recipient level is required (42 CFR 59.5(a)(9)).
- 8.4.8 Reasonable efforts to collect charges without jeopardizing client confidentiality **must** be made.
- A. At the time of services, clients who are responsible for paying any fee for their services should be offered bills directly. Bills to clients should show total charges less any allowable discounts. Sub-recipients must have the capacity to provide a bill to clients who request a bill.
 - B. Sub-recipients **must** have a method for the "aging" of outstanding accounts. Written policies on billing and collections **must** include a policy on aging accounts and writing off outstanding accounts.

8.4.9 Voluntary donations from clients are permissible; however, clients **must not** be pressured to make donations, and donations **must not** be a prerequisite to the provision of services or supplies.

8.5 Project Personnel

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

8.5.1 Sub-recipients **must** establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language. These policies should include, but are not to be limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures.

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

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

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

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

- A. Michigan's pharmacy law Act 368 of 1978 sec 333.17745 and 333.17745a. (Section I, pages 47, 48-50) requires that the physician who has responsibility for the dispensing of prescription medications at a service site have a Drug Control License delegating authority to dispense prescription drugs. The dispensing license is in addition to the medical license required for writing

prescriptions. A drug control license is required for each location in which the storage and dispensing of prescription drugs occur, in compliance with

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

- A. Physical assessment, diagnosis, treatment, and provision of medication and devices **must** be performed by a physician or licensed certified mid-level clinician.
- B. Non-directive pregnancy counseling for clients seeking medical information on options, including pregnancy termination **must** be provided by a physician or mid-level clinician. (42 CFR 59.14 (b)(1)(i) [Mar. 4, 2019]. Mid-level clinicians include nurse practitioners, certified nurse midwives, and physician assistants.
- C. All mid-level practitioners **must** maintain current licensure and certification by the standards defined by Public Act 368 of 1978 as amended, Part 4, R338.10406, as defined by the Michigan Department of Licensing and Regulation, Board of Nursing, in the General Rules, or by the Council of Allied Health Education (for the Certification of Physician Assistants); and that other health professionals and para-professionals may be utilized to perform non-medical responsibilities, or assist in medical functions as approved by the medical director.

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

8.6 Staff Training and Project Technical Assistance

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

- 8.6.1 Sub-recipients **must** provide for the orientation and in-service training of all project personnel, including the staff of sub-recipient agencies and service sites (42 CFR 59.5(b)(4)) and should provide periodic staff meetings to review program activities.
 - A. Sub-recipients **must** maintain documentation and attendance for required trainings for all staff and volunteers.
 - B. Sub-recipients should maintain documentation and attendance at continuing education programs for all staff.
 - C. All staff should be offered the opportunity to attend/access training programs, particularly Reproductive Health National Training Centers (RHNTC) programs, MDHHS training programs, and the annual Family Planning Update at least once per year.

- D. Funds for training and continuing education should be included in each year's operating budget.
- E. Registered nurses and mid-level practitioners should be offered appropriate educational opportunities so as to comply with requirements of the licensure/certification process.
- F. Sub-recipients are encouraged to participate in annual Family Planning Coordinator Meetings where needs for future training programs are discussed.
- G. Sub-recipients should have appropriate clinical resources available for staff such as: CDC Providing Quality Family Planning Services Recommendations of CDC and OPA; CDC U.S. Selected Practice Recommendations for Contraceptive Use, 2016 (SPR); Contraceptive Technology, 21st edition; and CDC, United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016.

8.6.2 Staff **must** be trained at orientation and annually on agency policies and procedures on mandatory reporting under Michigan's Child Protection law (CPL) and on intimate partner violence (IPV) and human trafficking.

- A. **Annual** training on agency mandated reporting policy and procedures **must** include the following:
 1. Review of the policy, including screening to identify situations that should be reported
 2. Assure that staff are aware that confidentiality under Title X may not be used to circumvent compliance with Michigan's CPL. (42 CFR 59.11)
 3. Review of procedures to be followed by staff responsible for filing a report and documenting the report with the appropriate agency administrator to assure compliance with the CPL and agency policy.
 4. Review of the process for documenting in the medical record that a report was made, including documenting of the minor's age.
- B. **Annual** training on the agency policy and procedures on intimate partner violence (IPV) should cover signs to identify potential victims of IPV or domestic abuse and of agency procedures to provide appropriate client education and counseling, assess client safety, and make referrals as needed.
- C. **Annual** training on agency policy and procedures on human trafficking should cover signs for identifying potential victims of human trafficking and agency procedures to address the concerns with clients, including assessment of danger and development of plan of care with client, resources, and required mandatory reporting if the client is a minor.

8.6.3 Staff **must** be trained on encouraging family involvement in the decision of minors to seek family planning services and on counseling of minors on how to resist being coerced into engaging in sexual activities at least every **two years**.

- 8.6.4 Staff **must** be trained regarding prevention, transmission and infection control in the health care setting of sexually transmitted infections including HIV as required by OSHA regulations.
- 8.6.5 Staff **must** be trained and understand their role in an emergency or natural disaster as required by OSHA regulations.
- 8.6.6 Staff **must** be trained in the unique social practices, customs and beliefs of underserved populations of their service area at least every **two years**.
- 8.6.7 Staff **must** be trained on content related to mandated reporting and human trafficking at least every **two years**. This training should be specific to identifying situations in a Title X clinic setting.
- 8.6.8 Clinical staff involved in dispensing medications **must** be trained regarding the nature and safety of pharmaceuticals dispensed in the clinic at least every **two years**.
- 8.6.9 At least one staff person **must** be trained to offer at least one type of fertility awareness-based method of contraception at each service site every **three years**.

8.7 Planning and Evaluation

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

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

9. PROJECT SERVICES AND CLIENTS

Projects funded under Title X are intended to enable all persons who want to obtain family planning care to have access to such services. Projects **must** provide for comprehensive medical, informational, educational, social, and referral services related to family planning for

clients who want such services. Sub-recipients **must** have written policies and procedures in place to assure the following:

- 9.1 Priority for project services **must** be to persons from low-income families (Section 1006(c) (1), PHS Act; 42 CFR 59.5(a) (6)).
- 9.2 Services **must** be provided in a manner which protects the dignity of the individual (42 CFR 59.5 (a) (3)).
- 9.3 Services **must** be provided without regard to race, sex, religion, age, national origin, color, height, weight, marital status, gender identification or expression, sexual orientation, number of pregnancies, partisan considerations, or a disability or genetic information. (42 CFR 59.5 (a) (4)), (MCL 37.2101 to 37.2804; MI Executive Directive 2019-09).
- 9.4 Projects **must** provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).
 - A. Projects **must** have policies and procedures in place to identify and address intimate partner violence.
 - B. Projects **must** have policies and procedures in place to identify and address victims of human trafficking.
- 9.5 Projects **must** provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5 (b)(8)).
- 9.6 All family planning services **must** be provided using written clinical protocols that are in accordance with nationally recognized standards of care, signed by the medical director responsible for program medical services. MDHHS will review protocols at the comprehensive program review.
- 9.7 All projects **must** provide for medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)).
 - A. Necessary referrals include but are not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursing the referral provider, but projects are not responsible for the cost of this care.

- 9.8 All projects **must** provide a broad range of acceptable and effective medically approved family planning methods (including fertility awareness-based methods) and services (including basic infertility services and services to minors). A service site that offers only a single or very limited number of family planning methods may participate only as part of a project where the entire project offers a broad range of family planning services. MDHHS **must** be informed of these arrangements (42 CFR 59.5(a) (1)).
- 9.9 Services **must** be provided without the imposition of any residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b) (5)).
- 9.10 Projects **must** provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a) (5)).
- 9.11 Projects may, but are not required to, offer pregnant clients nondirective pregnancy options basic information and counseling regarding the following options:
- A. Information on maintaining healthy pregnancy, importance of prenatal care
 - B. Information on adoption
 - C. Pregnancy termination.

If pregnancy options counseling beyond basic information is requested, and the project elects to provide this service, counseling must be provided by a physician or advanced practice provider using a nondirective client-centered approach. Projects must not perform, promote, refer for, or support abortion as a method of family planning, nor take any action to assist a client to secure an abortion. Projects must offer a client who is medically verified as pregnant with a referral for medically necessary prenatal health care. (42 CFR 59.13; 59.14).

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

10. CONFIDENTIALITY

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

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

11. COMMUNITY PARTICIPATION, EDUCATION, AND PROJECT PROMOTION

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

- 11.1 Title X grantees and sub-recipient agencies **must** provide an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).
- A. Sub-recipients **must** fulfill this requirement using a governing board, program specific family planning advisory committee (FPAC), or other appropriate advisory group which reviews general program/policy issues and make recommendations to the agency on organization, management and operation of the Family Planning Program.

1. The composition of the board or advisory committee **must** be broadly representative of the population served in the community and include persons knowledgeable about family planning.
2. Each group **must** meet at least once a year to:
 - a. Review the program plan, assess accomplishments, and suggest future program goals and objectives.
 - b. Review the progress toward meeting the needs population in the service area and maintaining services and policies responsive to the needs of the community.
 - c. The FPAC or advisory group, or a subcommittee of the FPAC or advisory group, may also serve the function of the Information and Education (I. & E.) Advisory Committee, so long as requirements of sections 12.1-12.7 are met.
3. Minutes **must** be kept of all meetings.
4. Meetings may be conducted utilizing electronic technology.

B. Other recommendations for community participation include the following:

1. Use of client satisfaction surveys.
2. Inclusion of teens and low-income clients on the Advisory Council.
3. Asking for client input on educational and informational materials.
4. Use of client surveys or focus groups designed to elicit what services may be seen as needed by clients but not available.

11.2 Projects **must** establish and implement planned activities to facilitate community awareness of and access to family planning services (42 CFR 59.5(b) (3)). Each family planning project **must** provide for community education programs (42 CFR 59.5(b) (3)). Community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

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

12. APPROVAL OF INFORMATION AND EDUCATION MATERIALS

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

12.1 Every sub-recipient **must** have a review and approval process of all informational and educational (I. & E.) materials developed or made available under the project prior to

their distribution to assure that the materials are suitable for the population and community for which they are intended and to assure their consistency with the purposes of Title X (Section 1006(d) (1), PHS Act; 42 CFR 59.6(a)).

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

- 12.2 I. & E. Committee membership **must** include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended (42 CFR 59.6 (b) (2)).
 - A. Family Planning Program staff may provide administrative and clinical support to the committee but may not be voting members of the advisory committee.
 - B. The committee may include professionals who work directly with population groups for which materials are intended, but the priority should be to include client and community members where possible.
 - C. The agency **must** demonstrate efforts to recruit client and community members to assure broad representation the populations served. See “Information & Education Committee Member Recruitment Tips and Resources” at: www.michigan.gov/familyplanning.
 - D. The description of I. & E. Committee composition submitted to MDHHS with the Annual Plan **must** include how the composition represents the populations served in terms of demographic factors such as race, color, national origin, handicapped conditions, sex, and age.
 - E. The I. & E. Committee roster submitted to MDHHS with the Annual Plan **must** identify what community populations/groups the member represents (e.g., agency or professional organization name, or teen, male, client, or parent).
- 12.3 The sub-recipient I. & E. Committee **must** be made up of five to nine members, except that this size provision may be waived by the Office of Population Affairs (OPA) where a good cause has been shown (42 CFR 59.6(b)(1)).
 - A. If a sub-recipient wishes to request a waiver to the requirement of five to nine memberships, a written request indicating the good cause reasons must be submitted to the MDHHS Family Planning Program consultant for MDHHS review and submission to OPA for approval.
- 12.4 MDHHS delegates the I. & E. materials review and approval process to the sub-recipients; however, the oversight responsibility of the I. & E. review process rests with MDHHS as the grantee. MDHHS monitors this committee and review process with the Annual Plan review and as part of the on-site comprehensive program review.

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

- A. A written description of the I. & E. Committee review and approval process **must** be included in a policy statement, by-laws, or other committee documents made available to members.
- B. All new information or education materials are distributed to committee members, along with a clinic brochure review form for each item, prior to the committee meeting. Sub-recipients should allow at least two weeks for members to review materials prior to a meeting.
 - a. The I. & E. Committee may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate staff; however, final responsibility for approval of the materials rests with the committee.
- C. The I. & E. Committee **must** use an MDHHS approved clinic brochure review form to document their review and individual determinations regarding approval for each educational material.
 - a. An approved clinic brochure review form is located on the MDHHS website at www.michigan.gov/familyplanning.
 - b. Sub-recipients wishing to modify or use a different form must submit it to their MDHHS program consultant for approval.
- D. At the I. & E. Committee meeting, members discuss their comments and recommendations and determine if the materials are appropriate for the intended community or target audience.
 - a. In their review of materials, the committee **must** consider the following:
 - i. The educational and cultural backgrounds of the individuals the materials are intended to serve
 - ii. The standards of the population or community the materials are intended to serve
 - iii. Review the content to assure that the information is factually accurate
 - iv. Determine whether the materials are suitable for the population or community they are intended to serve
- E. Committee approval of materials requires, at least one half of voting members.
- F. The I. & E. Committee **must** meet at least once a year; and should meet as often as is needed to review and approve new materials prior to their use. Meetings may be conducted utilizing electronic technology.

- G. A written record of the determinations and approval process **must** be established and maintained (Section 1006(d), PHS Act; 42 CFR59.6 (b)) including the following:
 - a. Minutes **must** be kept of all meetings and **must** reflect the determination for each item reviewed.
 - b. Completed review forms or a compiled summary of individual review forms **must** be maintained to document member determinations.
 - c. A master listing of materials that have been reviewed and approved by the committee with dates the items were approved/reapproved **must** be maintained.
 - H. Staff overseeing the I. & E. Committee are responsible to bring existing, previously approved, I. & E. materials for review or update on a timely basis to assure continued accuracy and appropriateness. Previously approved materials **must** be reviewed at least every three years.
- 12.5 Any publication or other media developed by the grantee or sub-recipient using Title X funds **must** acknowledge federal grant support (45CFR 74.36; Notice of Grant Award 6 FPHPA006464-01-01).
- A. Acknowledgement must include the following language: “This publication was supported by award no. _____ from the Office of the Assistant Secretary of Health (OASH). Its contents are solely the responsibility of the authors and do not necessarily represent the views of OASH.”
 - B. The current Title X grant award number under which the publication was produced must be identified in the acknowledgement of Title X grant support.

13. ADDITIONAL ADMINISTRATIVE REQUIREMENTS

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

13.1 Facilities and Accessibility of Services

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

Title X clinics **must** have written policies that are consistent with the HHS Office for Civil Rights policy document, *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (August 4, 2003) (HHS Grants Policy Statement 2007, II-23). (Section I, page38)

- A. Sub-recipients **must** ensure meaningful access to services for persons with limited English proficiency (LEP).
- B. Sub-recipients **must** have a written plan regarding the process for providing language assistance to LEP clients.
- C. The scope and complexity of the plan should consider the size of LEP populations likely to be encountered and frequency of contact with the LEP populations.
- D. LEP plans **must** include:
 - 1. Statement of the agency's commitment to provide meaningful access for LEP persons.
 - 2. Statement that services will not be denied to a client because s/he is limited English proficient.
 - 3. Statement that clients will not be asked or required to provide their own interpreter. The use of family and friends as interpreters is discouraged. If the client chooses to use family or friends, the client is informed of the right to free interpreter services and use of family or friends occurs only after the offer is declined and documented.
 - 4. LEP plans **must** include following:
 - a. Identify LEP individuals who need language assistance.
 - b. Language assistance, oral interpretation, and/or written translation
 - c. Staff training
 - d. Providing notice to LEP persons
 - e. Routine updating of the LEP plan

Sub-recipients **must not** discriminate on the basis of disability and, when viewed in their entirety, facilities **must** be readily accessible to people with disabilities (45 CFR part 84). (Section I, page 38,40)

13.2 Emergency Management

All grantees, sub-recipients, and Title X clinics **must** have a written plan for the management of emergencies (29 CFR 1910, subpart E), and clinic facilities **must** meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes). (Section I, page 40)

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

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

13.3 Standards of Conduct

Sub-recipients **must** establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7). (Section I, page 38)

13.4 Human Subjects Clearance (Research)

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

- A. MDHHS **must** approve human subject research through submission to the MDHHS Institutional Research Board (IRB) process.
- B. MDHHS will advise the OPA Regional Office in writing of any approved research project that involves Title X clients (HHS Grants Policy Statement 2007, II-9). (Section I, page 38)

13.5 Financial and Reporting Requirements

Sub-recipients **must** comply with MDHHS minimum reporting requirements, including the Office of Population Affairs (OPA) Family Planning Annual Report (FPAR) as described in the OPA FPAR Forms and Instruction manual at intervals specified by MDHHS. In addition, sub-recipients **must** have policies and procedures in place to follow Michigan mandatory reporting requirements under the Michigan Child Protection Act and compliance with Michigan's Human Trafficking law and **must** file an annual health care plan, (Section I, pages 51, 53, 58-59 and 60-62).

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

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

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

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

14. ADDITIONAL CONDITIONS

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

15. CLOSEOUT

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

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

Following closeout, the sub-recipient remains obligated to return funds due as a result of any later refunds, corrections, or transactions, and MDHHS may recover amounts based on the results of an audit covering any part of the period of grant support (HHS Grants Policy Statement, II-90). (Section I, page 38)

16. OTHER APPLICABLE HHS REGULATIONS AND STATUTES

The following HHS Department-wide regulations that apply to grants under Title X: (Section I, page 38)

- A. 37 CFR Part 401: Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
- B. 42 CFR Part 50, Subpart D: Public Health Service grant appeals procedure
- C. 45 CFR Part 16: Procedures of the Departmental Grant Appeals Board
- D. 2 CFR Chapter I, Chapter II, Part 200: Uniform administrative requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule. Federal Register December 26, 2013. This guidance streamlined requirements and supersedes HHS regulations (45 CFR Parts 74 and 92) and administrative requirements (A-110 and A-102), cost principles (A-21, A-87, and A-122), audit requirements (A-50, A-89, and A-133).
- E. 45 CFR Part 80: Nondiscrimination under programs receiving Federal assistance through HHS effectuation of Title VI of the Civil Rights Act of 1964
- F. 45 CFR Part 81: Practice and procedure for hearings under Part 80 of this Title
- G. 45 CFR Part 84: Nondiscrimination on the basis of disability in programs and activities receiving or benefitting from Federal financial assistance
- H. 45 CFR Part 91: Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- I. 45 CFR Part 100: Intergovernmental Review of Department of Health and Human Services Programs and Activities

The following statutes are applicable to grants under Title X: (Section I, pages 41-45)

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

SECTION III

Clinical Services

Clinical Services

17. INTRODUCTION

The MDHHS Title X Family Planning clinical guidelines were adapted from the Providing Quality Family Planning Services document (QFP), recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA). The QFP defines the provision of quality family planning services for people of reproductive age. The goal of family planning services is to assist individuals to achieve the desired number and spacing of children and to increase the chances that children will be born healthy. Quality family planning services include these attributes: confidentiality, safety, effectiveness, a client-centered approach to counseling, timeliness, efficiency, accessibility, equity and cost effectiveness. Quality Family Planning Services include the following core services:

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

Michigan Title X providers **must** offer all core family planning services listed above, related preventive health services (discussed on page 116) and referral for specialist care, as needed. Other preventive health services that are beyond the scope of Title X may be offered either on-site or by referral. Information on preventive health services recommendations is available from the U.S. Preventive Services Task Force <https://uspreventiveservicestaskforce.org/uspstf/>

All Title X projects **must** offer family planning services and related preventive health services to female and male clients, including minors. All projects **must** provide for medical services related to family planning and the effective use of contraceptive devices and practices including provider consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies, as well as necessary referrals to other medical facilities when medically indicated (42 CFR 59.5(b)(1)). This includes but is not limited to emergencies that require referral. (See referrals page 117) Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

18. SERVICE PLANS AND PROTOCOLS

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

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

19. PROCEDURAL OUTLINE

The services provided to family planning clients, and the sequence, in which they are provided, will depend upon the type of visit and the nature of the service requested. All the QFP services identified in the introduction **must** be offered to clients and documented in the medical record.

- A. Service delivery to all clients **must** include the following:
 - 1. Assuring clients are treated courteously and with dignity and respect.
 - 2. Professional recommendations for how to address the needs of diverse clients, such as Lesbian, Gay, Bi-sexual, Transgender, Questioning (LGBTQ) persons or persons with disabilities should be consulted and integrated into procedures, as appropriate. Providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services to minors should be provided in a "youth-friendly" manner.
 - 3. Assurance of confidentiality and the provision of privacy
 - 4. Opportunity to participate in planning their own medical treatment.
 - 5. Encouraging clients to voice any questions or concerns they may have.
 - 6. Materials and/or interpreter available for those with limited ability to read or understand English and for those who may be blind or hearing impaired.
 - 7. Explanation of all procedures, range of available services, and agency fees and financial arrangements.
- B. Individual client education **must** be offered.
- C. Individual counseling (a client-centered, interactive process to assist the client in making an informed choice) **must** be offered and/or provided prior to the client making an informed choice of family planning services.
- D. Services to minors **must** be offered and should be provided in a "youth-friendly" manner, making services accessible, equitable, comprehensive, and effective for youth. Counseling for minors **must** include the following:

1. Title X providers **must** offer confidential services to minors and **must** observe relevant state laws related to mandatory reporting of child abuse and neglect and human trafficking. (Section I pages 51-53)
 - a. Minors **must** be informed that services are confidential, except in special cases (e.g., child abuse) where reporting is required.
 2. Title X providers **must** encourage family involvement (communication between the minor and his/her parents, guardians, or trusted adult) about their decision to seek family planning services.
 3. Title X providers **must** provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.
 4. Title X required counseling for minor clients **must** be documented in the medical record.
 - a. If sub-recipients use checkboxes to document required counseling in the electronic health record, there **must** be associated counseling policies/protocols for each of these topics to clearly indicate the content covered.
 - b. If family involvement is not encouraged, the medical record **must** reflect the reason why, and in the case of suspected abuse or neglect, that a mandated report was made.
 5. Minors seeking contraceptive services **must** be provided comprehensive information about how to prevent pregnancy, including abstinence as an effective way to prevent pregnancy and STIs.
- E. Counseling for all clients **must** address the client’s pregnancy intention or reproductive life goals.
- F. The client’s general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2))
1. The general consent for services **must** state that services are confidential and voluntary; provided without coercion to accept services or any particular method of family planning and provided without prerequisite to accept any other service.
 2. The general consent for services **must** be language appropriate or obtained through an interpreter.
 3. If the encounter is a face-to-face visit, a written consent is required. If the encounter is a virtual or telehealth visit, a verbal consent for services must be documented in the client record.
- G. A medical history **must** be obtained that is appropriate to the type of service provided.
- H. A physical examination, including necessary clinical procedures, **must** be provided, as indicated.
- I. Laboratory testing **must** be provided, as indicated.
- J. Medications and/or supplies **must** be provided, as indicated/requested.
1. **Must** provide written specific instructions on how to use medications, if dispensed.
 2. **Must** include danger signs and when, where, and how to obtain emergency care, return schedule and follow-up
- K. Follow-up and Referral **must** be provided, as indicated.
1. Provision of referrals as needed
 2. Planned mechanism of client follow-up
 - a. Suggested return visit date

- b. Contact information for emergencies after hours
 - c. Discuss access to primary care services
- L. Emergency arrangements **must** be available for after hours and weekend care and should be posted, given to, and/or explained to clients.
- M. Return visits should assess the on-going plan of care and needed family planning related services.

20. CLIENT ENCOUNTERS

- A. The client’s general consent for services **must** be obtained prior to receiving any clinical services. (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a) (2))
 - 1. If the encounter is a face-to-face visit, a written consent is required. If the encounter is a virtual or telehealth visit, a verbal consent for services must be documented in the client record.
- B. Encounters with reproductive age clients may require different services (i.e., contraceptive services, pregnancy testing and counseling, achieving pregnancy, STI services and related preventive health services). For all clients, the following questions **must** be asked and documented to help determine what family planning services are most appropriate for the visit:
 - 1. **What is the client's reason for the visit?**
 - 2. **Does the client have another source of primary health care?**
 - 3. **Does the client have reproductive life goals or wants a pregnancy in the next year?**
 - a. Providers should assess the client’s reproductive goals and/or pregnancy intention by asking questions like: “Do you think you might like to have (more) children at some point?”, “When do you think that might be?”, “How important is it to you to prevent pregnancy (until then)?” or “Are you considering getting pregnant in the next year?”, or “Can I help you with reproductive health services today, such as birth control or preparing for a future pregnancy?” For guidance on client-centered reproductive goals counseling: <https://www.envisionsrh.com/path-framework>; https://rhntc.org/sites/default/files/resources/fpntc_eff_gs_path_card_2019-03.pdf or One Key Question guidance at <https://powertodecide.org/one-key-question>
 - b. Providers should encourage family involvement/partner participation in reproductive life planning and family planning decisions where possible and appropriate.
- C. Encounters with reproductive age clients should also include a zika risk assessment, including asking about past and future travel plans for the client and partner(s).
- D. In response to the COVID-19 public health emergency, CDC and HRSA guidance, OPA allowed virtual encounters in Title X clinics as of April 2020. Virtual family planning encounters providing access to family planning and related preventive health services, may include assessment, diagnosis, intervention, consultation, education, counseling, and

supervision. [COVID Emergency - Telemedicine in the Family Planning ProgramFP-06-20.pdf](#). Protocols should reflect changes in services in response to the COVID emergency.

Family Planning and Related Preventive Health Services for Women

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

Source: Centers for Disease Control and Prevention (CDC). (2014, April 25). Providing quality family planning services: Recommendations CDC and the U.S. Office of Population Affairs. *MMWR. Morbidity and Mortality Weekly Reports*. Retrieved from <http://www.cdc.gov/mmwr/pdf/rr/r6304.pdf>

Family Planning and Related Preventive Health Services For Men



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

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

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

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

² The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey, K, Navarro S, & Colechuck, M, Lu M. The clinical content of preconception care: preconception care for men. *Am J Obstet Gynecol*. 2008;199: [6 Suppl. 2]:S388-95).

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

⁴ Indicates that [CDC](#) suggests only for individuals at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

Note: These two charts provide a checklist of recommended family planning and related preventive health services (QFP pages 22, 23).

21. CONTRACEPTIVE SERVICES

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

A. Contraceptive services must include:

1. A broad range of FDA-approved contraceptive methods. All methods of contraception **must** have written protocols in place.
 - a. Current CDC Medical Eligibility Criteria (MEC) **must** be followed when prescribing contraceptives.
 - b. More than one method may be used simultaneously by the client (for example, a hormonal method and condoms or FABM and barrier method during the fertile period). Clients with high-risk sexual behavior patterns should be encouraged to use condoms correctly and consistently in addition to any other chosen method to reduce the risks of STIs/HIV and pregnancy.

B. Broad Range Contraceptives includes:

1. Hormonal Contraceptives
 - a. At least two delivery methods of combined hormonal contraceptives **must** be available on site.
 - b. At least one delivery method of progestin-only contraceptives **must** be available on site.
 - c. At least a second type of progestin-only method **must** be made available on site within two weeks of client request.
2. Condoms
 - a. At least male condoms **must** be available on site.
3. At least one type of long-acting reversible contraceptive (LARC) method **must** be provided, either on site or by paid referral.
4. At least one type of fertility awareness-based method (FABM) **must** be provided at each clinical site.
5. Education materials and information regarding all methods including, hormonal contraceptives, abstinence, fertility awareness-based methods, barrier methods, intrauterine devices, sterilization, and emergency contraception.
6. The agency formulary **must** indicate:
 - a. Methods maintained and available on site
 - b. Methods available on site within two weeks of client request
 - c. Methods available by paid referral.
 - d. Methods available by unpaid referral (i.e., sterilization)

7. Agencies **must** maintain a formal referral agreement for any required broad range method not provided on site.
8. A referral resource list should be provided for contraceptives not available in the clinic.
9. Agencies are encouraged to review current practice, needs and preferences of their client population and maintain the most frequently chosen methods where feasible.
10. Agencies are strongly encouraged to provide emergency contraception and maintain supplies on site.
11. Prescriptions may be written for contraceptives on the clinic formulary or on the client's insurance plan formulary. Accepting a prescription **must** not pose a barrier for the client.

C. Emergency Contraception

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

1. Written protocol must be in place.
2. If indicated by the client's history, a negative, highly sensitive pregnancy test is necessary to exclude a pre-existing pregnancy.
3. Birth control counseling should accompany or follow any method used for emergency contraception in order to discourage clients from using emergency contraception as a routine method of contraception.
4. Chlamydia testing must be offered to females <25 years of age and to females > 25 years with risk factors.

D. Permanent Contraception (Sterilization)

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

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

1. For a female client, the medical history **must** include:
 - a. Reproductive life goals
 - b. Menstrual history
 - c. Gynecologic history
 - d. Obstetrical history
 - e. Contraceptive use
 - f. Allergies
 - g. Medications

- h. Immunizations (use of the MI. Care Improvement Registry “MCIR” is strongly recommended)
 - i. Recent intercourse
 - j. Reproductive history
 - k. Infectious or chronic health condition (present)
 - m. Zika risk assessment
 - m. Other characteristics and exposures (e.g., age, postpartum, breastfeeding) that might affect the client's medical eligibility criteria (MEC) for contraceptive methods.
 - n. Social history/risk behaviors
 - o. Sexual history and risk assessment
 - p. Mental health
 - q. Intimate partner violence
 - r. Interest in Sterilization, if age appropriate (≥ 21 per federal law requirement)
2. For a male client, the medical history **must** include:
- a. Reproductive life goals
 - b. Use of condoms
 - c. Allergies (i.e., condoms)
 - d. Medications
 - e. Immunizations (use of the MI. Care Improvement Registry “MCIR” is strongly recommended)
 - f. Recent intercourse
 - g. Partner history (use of contraception, pregnant, has children, had a miscarriage or termination)
 - h. Infectious or chronic health condition (present)
 - i. Zika risk assessment
 - j. Contraceptive experiences and preferences
 - k. Sexual history and risk assessment
 - l. Interest in sterilization if age appropriate (≥ 21 per federal law requirement)

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

F. Physical and Laboratory Assessment

1. For a female client the following **must** be provided:
 - a. BP (when providing combined hormonal method and screening for hypertension)
 - 1) All clients—screen yearly
 - 2) If BP $<120/80$ —screen yearly, continue yearly
 - 3) If BP $120-139/80-89$ (either treated or untreated), recheck BP again in same visit if average BP $>140/90$ recheck at next visit or in 1 week and refer if sustained BP $>140/90$.
 - b. Bimanual exam and cervical inspection (prior to IUD insertion, fitting diaphragm or cervical cap)
 - c. Pap screening and clinical breast exam (based on current recommendations for timing and testing components). See Related Preventive Health Services section.

- d. Chlamydia testing **must** be offered annually for all females < 25 years, sexually active females \geq 25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year) (See page 113-114 in the STI section referencing the pre-paid forms)
 - e. CT and GC testing **must** be available for clients requesting IUD insertion, if indicated.
2. For a male client, laboratory tests are not required unless indicated by history.
 3. Referral for Zika screening if indicated.

G. Client-Centered Education and Counseling

Contraceptive counseling is to help a client choose a method of contraception and understand how to use it correctly and consistently. Clients (adults and minors) who are undecided on a contraceptive method **must** be informed about all methods that can be used safely based on the 2016 CDC Medical Eligibility Criteria. When educating clients about the broad range of contraceptive methods, information **must** be medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a manner that is readily understood and retained. Documentation of education/counseling **must** be in the client's medical record.

1. Educating clients about contraceptive methods they can use safely includes the following:
 - a. Method effectiveness
 - b. Correct and consistent use of the method
 - c. Benefits and Risks
 - d. Potential Side effects
 - e. Protection from STIs, including HIV
 - f. Starting the method
 - g. Danger signs
 - h. Availability of emergency contraception (provide on-site or by prescription)
 - i. Follow-up visit (as needed to obtain or maintain the selected method)
2. Quality client-centered contraceptive counseling includes the following:
 - a. Establish and maintain rapport
 - b. Assess the client's need and personalize the discussion
 - c. Work with the client to establish a plan
 - d. Provide information in a manner that can be understood by the client
 - e. Confirm the client's understanding
 - a. The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about effectiveness, risks, benefits, method use, protection from STIs and follow-up (QFP pages 45-46).
3. Contraceptive counseling must be documented in the client record (i.e., checkbox or written statement).
4. Client information sheets may be used for education.
5. When counseling male clients, discussion should include information about female-controlled methods where appropriate (including emergency contraception), encourage discussion of contraception with partners, and provide information about how partners

can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STIs, including HIV.

6. Encourage partner communication about contraception, including understanding partner barriers (e.g. misperceptions) and general support for using a chosen method.
7. A procedure consent form **must** be signed by the client prior to inserting an IUD or implant.
8. Clinical evaluation of a client electing permanent sterilization should be guided by the provider who performs the procedure.
9. Provide Zika education and prevention strategies.

H. Contraceptive Counseling for Minor Clients

Comprehensive information **must** be provided to minor clients about how to prevent pregnancy.

1. It should not be assumed that minor clients seeking family planning services are sexually active. Avoiding sex (abstinence) is an effective way to prevent pregnancy and STIs and can be chosen as a method at any time in life.
2. If the minor indicates that she or he will be sexually active, provide information about contraception and help her or him choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STIs/HIV. Long-acting reversible contraception (LARCs) are a safe and effective option for many minors, including those who have not been pregnant or given birth.
3. Title X providers **must** offer confidential services to minors and must observe state mandatory reporting laws related to child abuse, neglect and human trafficking (Section I, pages. 51-53).
 - a. Minors **must** be informed that services are confidential, except that in special cases (e.g., child abuse) reporting is required.
4. Title X providers **must** encourage communication between the minor and his or her parents, guardians or trusted adult about sexual and reproductive health and his or her decision to seek services.
5. Title X providers **must** provide counseling to minors on how to resist attempts to coerce them into engaging in sexual activities.

I. Counseling Returning Clients

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

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

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

J. Preventive Health Promotion and Referral

1. Title X providers should refer pregnant, parenting and postpartum minors to home visiting and other programs (MIHP, Nurse Partnership) that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy.

2. Title X providers should provide referral resources for mental health, domestic or intimate partner violence, and behavioral health including ETOH, tobacco, substance use as indicated.
3. Title X providers should provide a referral resource for immunizations as indicated.

22. PRECONCEPTION HEALTH SERVICES

Preconception describes anytime that a woman of reproductive potential is not pregnant but at risk of becoming pregnant, or when a man is at risk for impregnating his female partner. A written protocol and procedure **must** be current, available and consistent with national standards of care. Agencies **must** offer preconception health services to females and males as part of core family planning services. Preconception health services promote health before conception thereby reducing pregnancy-related adverse outcomes (low birth weight, premature birth, and infant mortality), promote birth outcomes and improve the health of male and female clients even if they choose not to have children.

The clinic visit includes:

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

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

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

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

10. Zika risk assessment

- C. Physical Examination for all clients:
 - 1. Height, weight, BMI (screen for obesity)
 - 2. BP (screen for hypertension- based on American Heart Assn. recommendations)
 - a. All clients—screen yearly
 - b. If BP <120/80---screen yearly, continue yearly
 - c. If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
- D. Laboratory testing
 - 1. STI/HIV testing as indicated
 - 2. Chlamydia testing **must** be offered annually for all females < 25 years, sexually active females \geq 25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year)
 - 3. Laboratory testing **must** be recommended based on risk assessment:
 - a. Diabetes screening (for type 2 diabetes in asymptomatic male and female adults) with sustained BP (either treated or untreated) >139/80 (USPSTF)
 - b. Referral for Zika screening if indicated.
- E. Client Plan/Education
 - 1. Some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife).
 - 2. Encourage to take a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
 - 3. Avoid smoking, alcohol and other drugs
 - 4. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
 - 5. Offer/Refer for any needed STI screening (including HIV)
 - 6. Refer for age-appropriate vaccinations, if indicated
 - 7. Provide Zika education and prevention strategies
- F. Referral:
 - 1. If client desires, refer for further diagnosis and treatment
 - 2. Refer male and female clients for additional services if screening results indicate presence of health condition or as indicated (i.e., tobacco cessation, obesity, diabetes, depression, immunizations).

23. ACHIEVING PREGNANCY SERVICES

A written protocol and procedure **must** be current, available, and consistent with national

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

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

A. Client assessment includes:

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

B. Medical history includes:

1. Immunizations
2. Medications
3. Present infectious or chronic health conditions
4. Genetic conditions
5. Environmental exposures
6. Social history/risk behaviors
7. Sexual health and risk assessment
8. Mental health
9. Medical history for **females must** Include:
 - a. Reproductive history
 - b. Obstetrical/Gynecology history
 - c. Family history
 - d. Intimate partner violence
10. Medical history for **males must** include:
 - a. Past medical or surgical history that might impair reproductive health
 - b. Medical conditions associated with reproductive failure that could reduce sperm quality

- C. Physical Assessment includes:
1. Height, weight, BMI (screen for obesity)
 2. BP (screen for hypertension)
 - a. All clients—screen yearly
 - b. If BP <120/80—screen yearly, continue yearly
 - c. If BP 120-139/80-89 (either treated or untreated), recheck BP again in same visit and if average BP >140/90 recheck at next visit or in 1 week and refer if sustained BP >140/90.
 3. No physical exam is needed for achieving pregnancy. Exams may be needed to evaluate problems raised by review of systems or complaints raised by the client.
 4. Assessment and updating the client's physical, sexual and medical history may reveal additional issues in the health history that need to be addressed. The results may indicate the need for information on fertility awareness or other health services: STI screening, preconception care, infertility services, and other preventative health services.
- D. Laboratory testing may include, as indicated based on client medical and sexual history
1. STI testing, including chlamydia testing offered for female clients ≤ 25 years.
 2. Diabetic screening
 3. Consider Zika screening if indicated by Zika Risk Assessment.
- E. Client education and counseling includes:
1. Importance of regular preventive health and chronic disease management
 2. Some medications might be contraindicated in pregnancy and current medications will need to be reviewed by the prenatal care provider (obstetrician, physician, or midwife)
 3. Encourage daily supplement containing (400-800 mcg) of folic acid or a prenatal vitamin
 4. Avoid smoking, alcohol and other drugs.
 5. Avoid eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish)
 6. Offer/refer for any needed STI screening, including HIV
 7. Offer/refer for age-appropriate vaccinations, as indicated
 8. Nutritional counseling and recommended weight loss if client is overweight
 9. Provide Zika education and prevention strategies
 10. Counseling provided **must** be documented in the record
- F. Education on maximizing fertility awareness and success includes:
1. Fertility awareness/ Techniques to predict ovulation
 - a. Education about peak days and signs of fertility (including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation)
 - b. Education on methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed

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

G. Referral

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

24. PREGNANCY DIAGNOSIS AND COUNSELING

Agencies **must** provide pregnancy diagnosis and counseling to all clients in need of this service (42 CFR 59.5(a) (5)). Pregnancy testing is one of the most common reasons for a first visit to a family planning agency. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning services. A written protocol and procedure **must** be current, available, and consistent with national standards of care.

A. Pregnancy diagnosis services include:

1. General Consent for Services
2. Reproductive Life Goals Discussion
3. Medical history (including chronic medical illnesses, physical disability, psychiatric illness)
4. Zika risk assessment
5. Pregnancy testing (qualitative urine with high sensitivity)
6. Pregnancy test results **must** be given to the client
7. Counseling and referral resource list as appropriate
8. Chlamydia testing **must** be offered to females < 25 years of age and to females \geq 25 years with risk factors.

B. If the **pregnancy test is positive**, the clinical visit should include:

1. An estimation of gestational age.
 - a. If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination may be needed to help assess gestational age.
2. Information on the normal signs and symptoms of early pregnancy
3. Instructions on when to report any concerns to a provider for further evaluation

4. Clients with a positive pregnancy test **must** be referred to a health care provider for medically necessary prenatal health care.
 5. If ectopic pregnancy or other pregnancy abnormalities or emergency situations are suspected, the client **must** be referred for immediate diagnosis and management.
 6. Title X sub-recipients **may not** perform, promote, refer for, or support abortion as a method of family planning. Nor can a sub-recipient take any affirmative action to assist a client secure an abortion.
 7. Sub-recipients should provide clients a list of comprehensive health care providers, including providers of prenatal care.
 - a. This list may include providers who perform termination as part of their comprehensive health care services. The list cannot contain a majority of providers who perform termination services and must not make any indication as to which providers conduct termination services.
 - b. Staff may not make any indication as to which providers conduct termination services.
 8. If there will be delays in obtaining prenatal care of more than 2 months, pregnant clients with risk factors should be offered STI testing (including HIV).
 9. Sub-recipients should assess the client's social support and provide appropriate counseling or social service resources.
- C. For clients with a positive pregnancy test, nondirective pregnancy options counseling may be offered.
1. Trained staff performing pregnancy testing may confirm the pregnancy and provide basic factual information regarding the client's pregnancy management options including:
 - a. Information on maintaining healthy pregnancy, importance of prenatal care, and pregnancy resources.
 - b. Information on adoption, including local or statewide resources; and
 - c. Acknowledgement that termination is an option, basic information on the procedures (medical and surgical), Michigan law and MDHHS Informed Consent for Abortion website.
 2. If the client needs or requests information beyond basic factual information, it may be provided by a physician or advanced practice provider (APP) using a client-centered nondirective approach. If the physician or APP is not on-site, sub-recipients can contact the provider by phone or other virtual mechanism.
- H. If a sub-recipient elects not to provide nondirective pregnancy options counseling, clients seeking to be counseled on their pregnancy management options may be referred to a program or health care provider who does provide this service. Use of this referral cannot

be used as an indirect means of promoting or encouraging abortion as a method of family planning.

- I. Information on maintaining a healthy pregnancy should include:
 - a. Advise that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy should be reviewed by a prenatal care provider.
 - b. Encourage a daily supplement containing (400-800 mcg) of folic acid (or a prenatal vitamin).
 - c. Encourage avoiding smoking, alcohol, and other drugs.
 - d. Encourage avoiding eating fish that might have high levels of mercury (e.g., King Mackerel, Shark, Sword fish, Tile fish).
 - e. Recommend age-appropriate vaccinations if indicated.
 - f. Recommend/refer for Zika screening if indicated.

- H. Clients with a **negative pregnancy test** and do not want to become pregnant **must** be offered information about family planning services as indicated, such as:
 1. The value of making reproductive life goals
 2. Contraceptive services (or scheduled for an appointment)
 3. Counseling to explore why the client thought she was pregnant and sought pregnancy testing services
 4. Assessed for difficulties using her current method of contraception, if indicated.

- I. Clients who are not pregnant and who are trying to become pregnant **must** be offered information about family planning, as indicated, such as:
 1. Services to help achieve pregnancy or basic infertility services
 2. Preconception health education
 3. STI services
 4. Reproductive life goals
 5. Zika education and prevention strategies

25. BASIC INFERTILITY SERVICES

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

- A. Infertility visit to a family planning clinic focuses on determining potential causes of the inability to achieve pregnancy and making any needed referrals for specialist care. Evaluation of both partners should begin at the same time. Earlier evaluation (6 months of regular unprotected intercourse) is justified for:
 1. Females aged > 35 years
 2. Those with a history of oligo-amenorrhea (infrequent menstruation)

3. Those with known or suspected uterine or tubal disease or endometriosis
 4. Those with a partner known to be sub-fertile (the condition of being less than normally fertile though still capable of effecting fertilization).
- B. An early evaluation may be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential
- C. Basic Infertility Care for Females. The infertility visit should focus on:
1. Understanding the client's reproductive life goals and difficulty in achieving pregnancy.
 2. The medical history **must** include:
 - a. Past surgeries
Previous hospitalizations
 - b. Serious illnesses or injuries
 - c. Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders)
 - d. Childhood disorders
 - e. Cervical cancer screening results and any follow-up treatment
 - f. Medication
 - g. Allergies
 - h. Social history/risk behaviors
 - i. Family history of reproductive failures
 - j. Reproductive history (i.e., time trying to achieve pregnancy, coital frequency and timing)
 - k. Level of fertility awareness
 - l. Previous evaluation and treatment results; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea
 - m. Sexual history (pelvic inflammatory disease, history of/exposure to STIs)
 - n. Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)
 - o. Zika risk assessment
 3. A physical examination **must** be offered if clinically indicated:
 - a. Height, weight, and body mass index (BMI) calculation
 - b. Thyroid examination (i.e., enlargement, nodule, or tenderness)
 - c. Clinical breast examination (CBE)
 - d. Signs of androgen excess
 - e. A pelvic examination (i.e., pelvic or abdominal tenderness, organ enlargement/mass; vaginal or cervical abnormality, secretions, discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity)
 - f. STI/HIV testing as indicated
 - i. Chlamydia testing must be offered for females < 25 and females \geq 25 with risk factors.
- D. Basic Infertility Care for Men. Infertility services provided to the male partner of an infertile couple should include:

1. Client's reproductive life goals
 2. Medical history **must** include:
 - a. Reproductive history (methods of contraception, coital frequency, and timing; duration of infertility, prior fertility; sexual history; and gonadal toxin exposure, including heat).
 - b. Medical illnesses (e.g., diabetes mellitus)
 - c. Prior surgeries
 - d. Past infections
 - e. Medications (prescription and nonprescription)
 - f. Allergies
 - g. Lifestyle exposures
 - h. Sexual health assessment.
 - i. Female partners' history (pelvic inflammatory disease, STIs, and problems with sexual dysfunction)
 - j. Zika risk assessment
 3. A physical examination **must** be offered if clinically indicated:
 - a. Examination of the penis (including the location of the urethral meatus)
 - b. Palpation of the testes and measurement of their size
 - c. Presence and consistency of both the vas deferens and epididymis
 - d. Presence of a varicocele
 - e. Secondary sex characteristics
 - f. STI/HIV testing, as indicated.
 4. Male clients concerned about their fertility should be offered a semen analysis via an unpaid laboratory requisition. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.
- E. Infertility Counseling
Counseling provided during the clinic visit is guided by information elicited from the client during the medical and reproductive history and findings from the physical exam. Provide Zika education and prevention strategies.
- F. Referral:
1. Clients (female and male) **must** be referred for further diagnosis and treatment if indicated or requested.
 2. Referral for Zika screening if indicated

26. SEXUALLY TRANSMITTED INFECTION SERVICES

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

- A. Assess client's reproductive life goals

- B. Medical history
 - 1. Allergies
 - 2. Medications
 - 3. Medical conditions
 - 4. Sexual health assessment, based on gender identify, current anatomy and sexual behavior (partners, practices, protection, past history of STIs, pregnancy prevention)
 - 5. Intimate Partner Violence
 - 6. Immunizations (Hep.B, HPV)
 - 7. Zika risk assessment
- C. Physical Exam as indicated (based on history or symptoms)
- D. Laboratory testing including the following:
 - 1. Chlamydia:
 - a. Testing **must** be offered annually for all females < 25 years. Sexually active females \geq 25 years with risk factors (infected partner, partner with other concurrent partners, symptoms, history of STI or multiple partners in the last year) should be offered testing-
 - b. Clients who test positive for Chlamydia should be re-tested 3 months following treatment for early detection of re-infection. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection.
 - c. Chlamydia screening for males can be considered at sites with high prevalence (adolescent clinics, correctional facilities, STI clinics) or males who have sex with males (MSM). Males with Chlamydia should be re-tested 3 months following treatment.
 - d. The MDHHS family planning program partners with the MDHHS STI Program by allocating pre-paid test forms for CT/GC to each sub-recipient agency based on population prevalence. These forms are intended for clients who are uninsured, underinsured or request confidential testing services. Use these pre-paid forms based on the following criteria:
 - 1) Priority goes to females under 25
 - 2) Based on historic positivity, males presenting in our publicly funded sites are eligible for testing with a pre-paid form
 - 3) Anyone needing a 90-day re-test is eligible for a pre-paid form
 - 4) Females \geq 30 may be tested using a pre-paid form only if:
 - a. Symptoms,
 - b. Infected partner,
 - c. History of STI (<3 years), or
 - d. Partner risk (new partner since last test, 3 or more partners in last year, partner with 3 or more current partners)
 - 2. Gonorrhea

- a. Testing **must** be offered annually to sexually active females <25 with high risks (previous gonorrhea, presence of other STIs, new or multiple sex partners, inconsistent condom use, commercial sex work, drug use) and those who reside in high prevalence areas. Other risk factors that place clients at increased risk include infected partner, symptoms, history of STI or multiple partners in past year.
 - b. All males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated.
 - c. Males who have sex with males (MSM) should be tested at sites of exposure. Clients with gonorrhea infection should be re-tested for re-infection 3 months after treatment. Clients who do not present at 3 months for re-test should be re-tested the next time they present for services in the 12 months following treatment of the initial infection.
 - d. Pre-paid IPP forms may be used for testing based on guidance provided above in 1.d.
3. Syphilis
- a. Testing should be offered to male and female clients at high risk:
 - 1) MSM,
 - 2) Commercial sex workers,
 - 3) Persons who exchange sex for drugs,
 - 4) Those in adult correctional facilities,
 - 5) Living in high prevalence areas).
4. HIV/AIDS
- a. Testing should be routinely recommended for all male and female clients 13-64 years of age.
 - b. Annual testing is recommended for high-risk individuals:
 - 1) injection drug users and their partners
 - 2) persons who exchange sex for money or drugs
 - 3) sex partners of HIV infected persons
 - 4) MSM or heterosexual persons who themselves or whose sex partner have had more than one sex partner since their most recent HIV test
 - c. Opt-out screening can be provided if included in the general medical consent.
5. Hepatitis C
- a. Testing should be recommended once for female and male clients without risks (if born during 1945-1965). If testing is positive, refer for additional care and management of HCV infection and related conditions. Assess for alcohol use and refer for intervention if indicated.
 - b. Clients with high-risk behaviors /conditions (e.g., past or current injection of illegal drugs, HIV infected) should be recommended to have annual testing.
6. Hepatitis B
- 1. Screening is not recommended for the general population.
 - 2. Testing should be recommended for high-risk populations (persons from high prevalence areas, HIV positive, IV drug users, MSM, Hep.B household contacts.)
7. Zika Virus
- 1. Risk assessment questions should be asked of all clients. Has the client or partner(s) traveled to a Zika impacted area in the past 8 months?

- 2. Consider referral for testing if sexually active and seeking pregnancy as appropriate.
- 3. All clients should be educated regarding Zika risks and prevention strategies
- J. STI treatment should be provided on-site. When treatment for any STIs provided on-site, the sub-recipient **must** follow current Centers for Disease Control and Prevention STI Treatment Guidelines ensure all clients are treated in a timely manner and appropriate follow-up measures are provided.
- F. Expedited Partner Therapy (EPT) should be offered as indicated for clients testing positive for chlamydia and gonorrhea.
 - 1. Michigan’s Public Act 525 of 2014 (MCL 333.5110) authorized the use of expedited partner therapy (EPT) for certain sexually transmitted infections as designated by the state department of health. The department designated chlamydia and gonorrhea as infections for which the use of EPT is appropriate. Guidance for providers and information for clients are available at <https://www.michigan.gov/hivsti> or see Section I, page 53, 54.
 - 2. As of April 15, 2020, MDHHS followed CDC guidance in response to the COVID-19 public health emergency to temporarily expand recommendations for EPT to include treatment for T. vaginalis (trichomoniasis) and for men who have sex with men (MSM) who are diagnoses with uncomplicated gonorrhea (GC). Dr. J Letter STD Options 4-15-2020.pdf
- G. Counseling
 - 1. Educate on risk reduction and available testing or referral for testing.
 - 2. Encourage vaccination for HPV and Hepatitis B if indicated
 - 3. Encourage condom use to prevent STI/HIV infection
 - 4. Encourage clients with STIs to:
 - a. Notify their sex partners and urge them to seek medical evaluation and treatment
 - b. Refrain from unprotected sexual intercourse during the period of STI treatment
 - c. Return for re-testing in 3 months if indicated
 - 5. Educate on Zika risks and prevention strategies
- H. Referral
 - 1. Clients with Hepatitis C and HIV infection should be linked to medical care and treatment.
 - 2. Clients should be referred for needed immunizations.
- I. Mandatory Reporting
 - 3. Sub-recipient agencies **must** comply with state and local STI reporting requirements.

27. GYNECOLOGIC SERVICES

Family planning agencies should provide for the diagnosis and treatment of minor gynecologic problems to avoid fragmentation or lack of health care for clients with these conditions. Written protocols and operating procedures **must** be available, current, and consistent with national standards of care. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine dip stick testing.

28. RELATED PREVENTIVE HEALTH SERVICES

Written protocols and operating procedures **must** be available, current, and consistent with national standards of care. All sub-recipient agencies **must** comply with the current MDHHS Family Planning Breast and Cervical Cancer Screening Protocols and **must** participate in the Family Planning/Breast and Cervical Cancer Control Navigation Program (FP/BC3NP) Joint Project for diagnostic services (i.e., breast ultrasound, mammogram, and colposcopy) for uninsured or underinsured clients. Coordination of care **must** go through the BC3NP Coordinator unless other referral/payment arrangements are in place. Family Planning projects are encouraged to refer eligible clients to the BC3NP program for cervical screening where appropriate.

- A. Clinics **must** offer and/or provide and stress the importance of the following to all clients:
 - 1. Clinical Breast Exam (CBE) performed at least every three years for average-risk asymptomatic clients beginning at age 25 through age 39, and annually for females \geq 40 years of age.
 - 2. Pap testing as indicated:
 - a. Age 21 to 64, every 3 years if Pap test is negative, OR
 - b. Age 30 to 64, every 5 years if using co-testing (pap and HPV) and both are negative
 - c. Age 30 to 64, every 5 years if using HPV-HR test alone
 - d. Cervical follow-up care provided for clients according to the 2019 ASCCP Cervical Risk-Based Management Guidelines. <https://www.asccp.org/mobile-app>
 - 3. Pelvic examination (including vulvar evaluation and bimanual exam) should be performed with routine pap testing and **must** be provided if medically indicated.
- B. Clinics **must** stress the importance of mammography screening:
 - 1. Females age 40-64 years at average risk for breast cancer on an annual basis.
 - 2. Screening for females age 25-64 at high-risk for breast cancer should be based on the client's risk factors. (NCCN 2018 screening recommendations for females at increased risk)
- C. Clinics should conduct a genital examination for minor males and document:
 - 1. Skin and hair distribution (observation)
 - 2. Hydrocele, varicocele, (observation and palpation)
 - 3. Signs of STI (observation and/or palpation)

29. QUALITY MANAGEMENT

A. Referrals and Follow-up

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

1. Referral procedures **must** be sensitive to clients' concerns for confidentiality and privacy.
2. Client consent for release of information to providers **must** be obtained, except as may be necessary to provide care or as required by law
3. Protocols and operating procedures for referrals and follow-up made as a result of abnormal physical examination or laboratory test findings within the scope of Title X that impact contraceptive management **must** include the following:
 - a. A system to document referrals and follow up procedures **must** be in place.
 - b. Follow-up procedures **must** include the following:
 - 1) A method to identify clients needing follow-up
 - 2) A method to track follow-up results on necessary referrals (such as, Pap and breast follow-up)
 - 3) Documentation in the client record of contact and follow-up.
 - 4) Documentation of reasons, actions and follow-up where recommendations were not followed and/or protocols not acted upon.
 - c. Referral procedures should include that the client be given an explanation of the referral and need for follow-up including:
 - 1) Reason and importance of the referral
 - 2) Services to be received from the referral agency
 - 3) Address of the referral provider/agency
 - 4) Any instructions needed to follow through with the referral
 - 5) When to return to the family planning clinic
4. Sub-recipient agencies **must** provide all Quality Family Planning Service components either on-site or by referral. When required services are provided by referral, the agency **must** have in place formal arrangements with a referral provider that includes a description of the services provided and includes cost reimbursement information.
5. For services determined to be necessary but which are beyond the scope of the project (such as thyroid abnormalities), clients **must** be referred to other providers for care. When a client is referred for non-family planning or emergency clinical care, agencies **must**:
 - a. Document that the client was advised of the referral and the importance of follow-up
 - b. Document that the client was advised of their responsibility to comply with the referral
6. Sub-recipients **must** maintain a current referral list that includes health care providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs.
 - a. Referral lists **must** be current and updated annually
 - b. When possible, clients should be given a choice of providers

B. Pharmaceuticals

Agencies **must** operate in accordance with Federal and state laws relating to security and record keeping for drugs and devices. The inventory, supply, and provision of

pharmaceuticals **must** be conducted in accordance with state pharmacy laws and professional practice regulations.

It is essential that each facility maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients. Projects should also ensure access to other drugs or devices that are necessary for the provision of other medical services included within the scope of the Title X project. Agencies are allowed to write prescriptions for Title X clients who choose and can conveniently obtain their contraceptives and medications from a pharmacy. Prescriptions may be written for contraceptives/medications on the clinic formulary or on the client's insurance plan formulary.

1. The medical director of the family planning program is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals. Written protocols and operating procedures for the distribution, security and record keeping of pharmaceuticals and supplies **must** be in place.
2. Prescription of pharmaceuticals is done under the direction of a physician (who **must** have a drug control license for each location in which the storage and the dispensing of prescription drugs occur). The physician may dispense indirectly under his/her delegated authority to a R.N. or certified mid-level clinician. Pre-labeled, pre-packaged oral contraceptives may be distributed if delegated by a dispensing prescriber.
 - a. All medications dispensed in Title X clinics **must** be pre-packaged.
 - b. Prescription medications dispensed (including samples) **must** be labeled and labels **must** contain the following information:
 - 1) Name and address of location from which the prescription drug is dispensed
 - 2) Name of the client, unless prescription is authorized for EPT
 - 3) Date the prescription drug is dispensed
 - 4) Name, strength, and quantity of drug dispensed
 - 5) Directions for use, including frequency of use
 - 6) Prescriber's name
 - 7) Expiration date of prescription drug
 - 8) Client 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 training pertaining to the nature and safety aspects of pharmaceuticals is provided at least every two years to staff involved in the provision of medications to clients (i.e., new staff orientation, staff meeting, and quiz).
3. Under Public Health Code Act 368 of 1978, a dispensing prescriber may only dispense drugs to his/her clients, with the exception of dispensing prescriptions for expedited partner therapy (EPT) as authorized in section 5110 or section 17744a/17744b under Pharmacy Practice and Drug Control (333.17745)

[http://www.legislature.mi.gov/\(S/wjwslol3kv501nx23qrash4c\)/mileg.aspx?page=getObject&objectName=mcl-333-17745](http://www.legislature.mi.gov/(S/wjwslol3kv501nx23qrash4c)/mileg.aspx?page=getObject&objectName=mcl-333-17745)

4. The inventory, supply and provision of pharmaceuticals may be delegated to appropriate qualified health professionals.
 - a. Family planning health professionals delegated to deliver prescriptions drugs **must** be trained in all aspects of pharmaceutical and supply distribution.
 - b. Delegate agencies **must** have proper segregation between requisition, procuring, receiving and payment functions for pharmaceuticals and supplies.
 - c. Delegate agencies **must** have an inventory system to control purchase, use, reordering of pharmaceuticals and supplies.
 - d. Delegate agencies **must** have adequate controls over access to medications and supplies including:
 - 1) Contraceptive and therapeutic pharmaceuticals **must** be kept in a secure place, either under direct observation or locked.
 - 2) Access to pharmaceuticals **must** be limited to health care professionals responsible for distributing these items.
 - 3) Safeguards **must** be in place for assuring that supplies purchased through the 340 B program are provided only to clients of the family planning program.
 - e. A system **must** be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs.
 - f. A system for silent notification in case of drug recall **must** be in place.
 - g. Inventory levels should not exceed a six-month supply.
5. 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.
6. An adequate supply and variety of drugs and devices **must** be available to meet their client's contraceptive needs.
 - a. Purchase and use of generic drugs based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalence accepted by the State Board of Pharmacy is acceptable.
 - b. Sub-recipient agencies may elect to identify certain supplies on the formulary, such as more expensive or infrequently used methods, that will be ordered upon client request and be available within two weeks of the request.
7. 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.
8. Prescriptive Methods for Transfer Clients
 - a. An informed (general) consent form **must** be obtained, and a client history **must** be completed/reviewed. A BP **must** be taken if the client desires to continue on a combined hormonal contraceptive. The provider will review the transfer records and decide if current prescription can be continued. The provider **must** document the prescription in the client's record.

C. Medical Emergencies

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

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

D. Medical Records

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

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

 - a. Personal data:
 - 1) Name
 - 2) Address, phone number(s), and how to contact

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

E. Quality Improvement

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

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

- j. Periodic monitoring for reliability and accuracy of the client data system to assure program performance, reporting, quality care, and generation of revenues. The following components should be monitored:
 - 1) Missing user data
 - 2) Coding errors
 - 3) Data outcome
- 4. A Quality Improvement Committee should be in place. This committee should meet monthly to discuss quality assurance issues and to make recommendations for corrective action when deficiencies have been noted.
 - a. If a formal Quality Improvement Committee is in place, minutes should be kept of all committee meetings.
 - b. The function of the Quality Improvement Committee may be assumed by an in-house nursing or medical advisory committee with ongoing documentation of quality improvement activities.

SECTION IV

Program Monitoring

A. ACCREDITATION AND SITE REVIEWS FOR TITLE X FAMILY PLANNING PROGRAMS

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

The MDHHS Title X Family Planning Program Standards and Guidelines is the primary resource that outlines what is needed to meet Title X program requirements. The following resources are consistent in these program expectations: The Federal Register Title X [42 CFR Part 59, Subpart A], the Family Planning Statute which defines the legislative requirements for the program. The OPA Title X Program Requirements, consisting of program requirements based on the 2019 Title X Rule “Compliance with Statutory Program Integrity Requirements,” 84 Fed. Reg. 7714 (Mar. 4, 2019) and Providing Quality Family Planning Services (QFP) are the guidance issued to grantees to direct implementation of the program. These are available on the OPA website and in the federal resource section of this document. The MDHHS Title X Family Planning Standards and Guidelines provide the most detailed and specific expectations, considering Michigan laws and Michigan specific requirements.

Accreditation Reviews for Local Public Health Department Family Planning Programs

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

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

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

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

Methods

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

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

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

Process

The following are steps in the site review process:

1. The MPR Indicator Guide for Family Planning, list of required Pre-Materials and Fiscal Questionnaire are available at the MDHHS Family Planning website or on the MPHI Local Public Health Accreditation website:
 - a. www.michigan.gov/familyplanning
 - b. <https://accreditation.localhealth.net/>
2. Pre-Materials are to be submitted to the MDHHS Family Planning program at six weeks prior to the scheduled review. The materials may be submitted either electronically or mailed in a storage drive, or hard copy.
3. Unless otherwise requested by the program, the family planning coordinator serves as the contact with MDHHS for the review process.
4. Agencies have the option to request a pre-accreditation conference call or meeting to ask questions as they prepare for the site review.
5. The on-site program review is a two-day process. Programs **must** have at least one clinic session scheduled during the visit to facilitate the evaluation of administrative and clinical

components of the program. Programs are encouraged to schedule clinic sessions on the initial day of the site review, if there are not clinics on both days.

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

B. TECHNICAL ASSISTANCE AND MONITORING VISITS

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

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

C. MDHHS PROGRAM AUDITS

The Bureau of Audit, Reimbursement, and Quality Assurance is responsible for conducting financial audits of one third of sub recipient agencies each year and managing Single Audit information sent in by third party auditors for agencies expending over \$750,000 in Federal grant funding. (Section I, page 62,63)

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

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

SECTION V

MDHHS and National Title X Training Programs

A. MDHHS COORDINATORS MEETING

Two regional Family Planning Coordinators Meetings are held annually to update all family planning coordinators throughout the State. These face-to-face meetings provide a venue for sharing pertinent information related to program and policy issues or changes. In addition, essential information is presented from the Michigan Department of Health and Human Services management, administrative and clinical consulting staff regarding clinical and management issues pertinent to Title X Family Planning clinics. The Family Planning Coordinators Meetings are also used to assess ongoing and future training needs for the network.

These two regional meetings are coordinated by the Michigan Public Health Institute (MPHI) and the Michigan Department of Health and Human Services. The regional meeting format replaced a single webinar format to allow for broader agency coordinator participation and to enhance needed networking among programs.

B. MICHIGAN ANNUAL FAMILY PLANNING UPDATE

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

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

C. ADDITIONAL MDHHS STAFF AND SUB-RECIPIENT TRAININGS

In addition to the coordinator meetings and family planning conference, MDHHS in cooperation with MPHI, provides a number of other training opportunities related to family planning throughout the year. These trainings are provided through a combination of face-to-face

workshops and webinar offerings. Continuing education and contact hours are available where possible.

MPHI publishes a calendar online with all the educational offerings for the year. This calendar is available on the MPHI website. Visit the MPHI website for more information and registration: <https://events.mphi.org/calendar/>

Participant evaluations are collected after each workshop and training to provide information from the previous year for planning future meetings and trainings. Trends in requests for information, suggestions for improvement and for future trainers, as well as other information obtained through these evaluations are considered in the planning.

D. NATIONAL MEETINGS, CONFERENCE AND NATIONAL TRAINING CENTERS (NTCS)

The National Family Planning Program authorized in 1970 as Title X of the Public Health Service Act (P.L.910572). The nationally funded Title X program is administered by the Office of Family Planning in the Office of Population Affairs within the Department of Health and Human Services. Information about the Family Planning program is available on the OPA Website at: <https://opa.hhs.gov/grant-programs/title-x-service-grants>

The Title X program, under Section 1003, provides training grants for personnel working in family planning services projects, with the purpose of promoting and improving the delivery of family planning services. OPA funds two training centers:

1. The Reproductive Health National Training Center (RHNTC) works in collaboration with OPA and the Office on Women's Health (OWH) to address the needs of Title X family planning service grantees and providers and Teen Pregnancy Prevention (TPP) grantees and program staff. <https://rhntc.org>
2. The National Clinical Training Center (CTC) provides clinical training for nurse practitioners, certified nurse midwives, physicians, and physician assistants. The CTC develops annual national family planning training symposiums, a national biennial reproductive health conference, and clinical webinars including "virtual coffee breaks." <https://www.ctcfp.org/>

MDHHS maintains a health system membership to the National Family Planning and Reproductive Health Association (NFPRHA) that includes member privileges for the FP Coordinator of each Title X sub-recipient. Member privileges include access to NFPHRA webinars, conferences, member calls and many resources on practice and program issues of importance to Title X providers. NFPRHA promotes and supports the work of family planning providers and administrators such as Title X. <https://www.nationalfamilyplanning.org/>

E. 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 and reproductive health 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 improves the well-being of individuals and families. Towards that end, individuals representing the state government, local health departments, Planned Parenthoods, hospitals, adolescent health centers, advocacy agencies, and community members have joined together to enhance access to family planning services.

History

MDHHS has received Title X Family Planning funding for the state of Michigan since 1972. The Title X Program is the only federal program devoted solely to the provision of family planning and reproductive health care. Title X Grantees are required to have community participation in the program by persons broadly representative of significant elements of the population served and by persons knowledgeable about the community's needs for family planning services. Since 1972, Michigan has met this requirement through the statewide FPAC. During much of this time, Title X providers were among few sources of family planning care for low-income people in Michigan. Today, federally qualified health centers throughout Michigan provide low-cost health services including family planning. In 2006, Michigan Medicaid was approved to provide expanded family planning coverage to low-income females through a Medicaid waiver program, called Plan First! expanding access for many. In 2014, Michigan implemented the Affordable Care Act's (ACA) Medicaid Expansion, called the Healthy Michigan Plan. Under this plan, Medicaid coverage, including family planning, is available to adults with income up to 138% of the federal poverty level. After the successful rollout of the Healthy Michigan Plan, the Plan First! Waiver program was phased out in 2016. As of April 12, 2021, there were more than 900,000 people enrolled in the Healthy Michigan Plan. FPAC has consistently supported these efforts to expand access to care in Michigan.

During the summer of 2020, the FPAC completed a strategic planning process to define a clear vision for family planning in Michigan, the role of FPAC in achieving that vision, and identify specific actions to work toward the vision. While Title X programs remain the cornerstone of family planning services, the FPAC continues to focus on all providers of family planning and reproductive health care for low-income Michiganders. FPAC members identified three major themes in its vision for Michigan:

- **Contraceptive Availability:** Work towards Increase availability of condoms and comprehensive contraceptive access through distribution, affordability, insurance coverage, and over-the-counter options
- **Access and utilization of care:** Address the need for dependable, affordable, and accessible reproductive health care.

- **Awareness of Reproductive Health Services:** Provide the general public a greater awareness of family planning, its services and programs through public health messaging and campaigns that can be understood by all.

Shared Vision:

The vision of FPAC is that all Michigan communities have equitable access to comprehensive, affordable, inclusive, and affirming sexual and reproductive health services with a focus on quality and innovation.

Selected FPAC Roles:

- Promote the need for policy changes to increase available services and make them easier to access, including contraceptive availability in schools.
- Expand innovative, accessible sexual and reproductive health care through the promotion of telehealth services and “Contraceptive Access Best Practices.”
- Raising community awareness of sexual and reproductive health services by providing resources and information to organizations serving Michiganders (schools, community orgs, consumers, providers, and those who link consumers with providers).

Participants

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

Structure

The FPAC meets three times per year. The FPAC agenda is carried forward through the work of the following sub-committees.

- Policy and Advocacy: Promote the need for policy changes to increase available services and make them easier to access
- Promotion and Education: Promote and provide the general public a greater awareness of family planning services and programs through public health messaging and campaigns that can be understood by all.
- Service Delivery: Expand innovative, accessible sexual and reproductive health care through the promotion of telehealth services and contraceptive access best practices