Section IX: Family Planning

MPR 1

Provide Family Planning services following Title X Requirements for provision of services: Services must be voluntary, provided without any coercion, provided in a client-centered manner that protects the dignity of the individual, provided without discrimination, with priority to individuals from low-income families, without residency or referral criteria, with safeguards for the privacy and confidentiality of individuals being served (Tenets of Title X Services)

References: *42 CFR (10-2021 edition) §59.5 (a)(2)-(6); 42 CFR §59.5 (b)(5); 42 CFR §59.10; Health Insurance Portability and Accountability Act of 1996 (HIPAA);* ***The*** *Privacy Act of 1974****,*** *5 U.S.C. § 552a; Elliott-Larsen Civil Rights Act, 1976 PA 453, as amended, MCL 37.2101 to 37.2804, Executive Directive 2019-09*

Indicator 1.1

Voluntary. Services must be provided solely on a voluntary basis, without any coercion to accept services or accept any particular methods of family planning. Acceptance of services must not be made a prerequisite to eligibility or receipt of services or participation in any other program.

See Michigan Title X Family Planning Standards & Guidelines **(8.1; 8.1.A, B, C, D; 19.F.1; 20.A; 29.D.2.e)**

To fully meet this indicator:

- The agency providing family planning services assures that services will be provided to clients:
  - On a voluntary basis **(8.1)**
  - Without coercion to accept services or any particular method of family planning **(8.1.A; 19.F.1)**
  - Without making acceptance of services a prerequisite to eligibility for any other service or assistance in other programs **(8.1.B)**
- The agency general consent for services includes that 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. **(8.1.D; 19.F.1)**
- The client's voluntary general consent must be obtained prior to receiving any clinical services. All consents are included in the client's record. **(19.F; 20.A; 29.D.2.e)**
- Staff have been informed that they may be subject to prosecution under federal law if they coerce or try to coerce any person to accept abortion or sterilization. **(8.1.C)**

Documentation Required:

- Policy and procedures that address voluntary participation without coercion, eligibility, or prerequisite.
- Agency general consent for services form
- Documentation that staff has been informed of the possibility of prosecution if they coerce any client to accept abortion or sterilization.

Evaluation Questions:

- Are there written policies in place that reflect that all services are voluntary, provided without coercion, and provided without making acceptance of services a prerequisite to eligibility for any other service or assistance in other programs?
- Does the agency general consent for services include that services are voluntary, provided without coercion, and provided without a prerequisite to accept any other service?

Indicator 1.2

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Dignity & Respect. Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive and trauma-informed which protects the dignity of the individual.

See Michigan Title X Family Planning Standards & Guidelines **(8.5.2;9.2;13.1;13.4;13.4.A;19.A.1-6;29.D.3e, f)**

To fully meet this indicator:

- The agency provides services in a client-centered manner that protects the dignity of each individual. **(9.2; 19.A.1-6)**
- Has written policy and/or procedures to assure that services are client-centered, culturally and linguistically appropriate, inclusive and trauma-informed. **(9.2; 8.5.2;13;19.A.1.)**
- Service delivery to all clients includes the following: **(19.A)**
  - Assuring clients are treated courteously and with dignity and respect
  - Addressing the needs of diverse clients
  - The opportunity to participate in planning their own medical treatment
  - Encouraging clients to voice any questions or concerns they may have
- Provide an explanation of range of available services, and agency fees and financial arrangements to clients **(19.A.6)**
- Upon request, clients are given access to or provided a copy of their medical record. **(29.D.3.e, f)**
- The agency obtains Michigan Department of Health and Human Service (MDHHS) approval prior to conducting any clinical or sociological research using Title X clients as subjects. **(13.4; 13.4 A)**

Documentation Required:

- Policy and Procedure Manuals
- Client records
- Client bill of rights or other documents outlining patient rights and responsibilities
- Client Satisfaction Surveys

Evaluation Questions:

- Do policies and procedures address treating clients with dignity and respect for diverse cultural and social practices, and assure client confidentiality?

Indicator 1.3

Non-Discrimination. Projects must provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, marital status, partisan considerations, disability or genetic information. Projects must provide services without imposing any residency requirements or requiring the patient be referred by a physician.

See Michigan Title X Family Planning Standards & Guidelines **(9; 9.3; 9.9; 13.1; 13.1.D.1-4;13.5. A.1-2; 19.A.6; 19.F.2)**

To fully meet this indicator:

- The agency has written policies and procedures on non-discrimination in providing services without regard to religion, race, color, national origin, disability, age sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, marital status, partisan considerations, disability or genetic information. **(9; 9.3)**

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- There is a written policy that services are provided without residency requirements or physician referral. **(9.9)**
- The agency complies with [45 CFR Part 84], so that, when viewed in its entirety, the agency is readily accessible to people with disabilities **(13.1)**
- The local agency has a written plan including all required components to ensure meaningful access to services for persons with limited English proficiency **(13.1.D. 1-4)**
- Consent forms are language appropriate for Limited English Proficiency (LEP) clients or are translated by an interpreter. **(13.1.D.4; 19.B.1; 19.F.2)**
- The agency complies with the Office of Population Affairs FPAR requirements, including a system to assure accurate collection of race and ethnicity data (FPAR Tables 2 and 3) **(13.5.A.1,2)**

Documentation Required:

- Non-discrimination policy, including policy on residency and physician referral
- Copy/location of agency's posted or distributed non-discrimination policy
- LEP plan
- Consent forms written in languages other than English, as appropriate
- Client demographic data form

Evaluation Questions:

- Are facilities accessible to individuals with disabilities including:
  - Entrance ramps are clearly marked and easily accessible?
  - Toilets accessible to the handicapped?
  - Handicapped parking?
- Does the LEP plan include:
  - A statement of agency's commitment to provide meaningful access to LEP individuals?
  - A statement that services will not be denied to clients because of LEP?
  - A statement that clients will not be asked or required to provide their own interpreter?
  - Language Assistance, oral interpretation, and/or written translation?
  - Providing notice to LEP persons?
  - Routine updating of the LEP plan?
  - Staff training?
- Is there a policy prohibiting residency requirement and physician referral?

Indicator 1.4

Priority to Low-income Populations. Provide that priority in the provision of services will be given to persons from low-income families

See Michigan Title X Family Planning Standards & Guidelines **(5; 8.4; 9.1)**

To fully meet this indicator:

- The agency has written policies and/or procedures to assure that no one is denied services or is subject to any variation in quality of services because of inability to pay **(8.4)**
- Low-income and high priority populations to be served are identified in the agency's annual plan **(5; Section 1.B Annual Health Care Plan Guidance)**
- Have policy and/or procedures to ensure that low-income clients are given priority to receive services **(9.1)**

Documentation Required:

- Sliding fee scale
- Non-discrimination policy for ability to pay

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- Policy and/or Procedures that assure low-income clients are prioritized

Indicator 1.5

Confidentiality. Projects must have policies, procedures and safeguards to protect client confidentiality. Information obtained about individuals receiving services must not be disclosed without the individual's documented consent, except as required by law or as necessary to provide services to the individual. Information may otherwise be disclosed only in summary, statistical or other form that does not identify the individual. *(from old MPRs 3&11.6)*

See Michigan Title X Family Planning Standards & Guidelines **(10.1.A, B, C; 10.2; 10.3; 19.A. 3; 19.F.1; 21. H.3; 29.D.1.c; 29.D.3.a-f)**

To fully meet this indicator:

- Client confidentiality is assured by the following: **(10.1. A., B., C.; 19.A.3; 19.F.1; 29.D.3a)**
  - Confidentiality is assured in agency policy and procedures
  - A confidentiality assurance statement appears in the general consent for services in the client record.
  - All agency personnel assure confidentiality, such as a confidentiality statement
- The clinic has safeguards to provide for the confidentiality and privacy of the client as required by the Privacy Act. **(10.1,10.2; 29.D.3.a-f)**
- HIPAA regulations regarding personal health information are followed. **(29.D.1.c)**
- Systems are in place to keep client records confidential. **(29.D.1.b.4; 29.D.3)**
- The agency does not disclose client information without the client's consent, except as required by law or as necessary to provide services. **(10.2; 29.D.3.c)**
  - Agency general consent informs clients of potential disclosure of health information to a policyholder if the policyholder is someone other than the client. **(10.2.A; 21.H.3.a-c.)**
  - The agency provides confidential services to minors and observes all state laws regarding mandatory reporting and informs minors of situations of potential disclosure. **(21.H. 3; See under Indicator 9.1**)
- Information collected for reporting purposes is disclosed only in summary or statistical form **(10.3; 29.D.3.d)**

Documentation Required:

- Policy and Procedure Manuals
- Client records
- General Consent for Services

Evaluation Questions:

- Does the physical layout of the clinic ensure that services are provided in a way that protects confidentiality and privacy?

MPR 2

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

References: *42 CFR §59.5 (b)(4); MDHHS Michigan Title X Family Planning Standards & Guidelines; CFR Part 84; 29 CFR Part 1910 Subpart E.*

Indicator 2.1

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Staff Orientation and Training. Provide for orientation and in-service training for all project personnel

See Michigan Title X Family Planning Standards & Guidelines (8.5.1.A-D; 8.5.3; 8.5.4; 8.6.1-9; 13.2; 18.B; 29.B.2.d; 29.B.3.a; 29.C; 29.C.3 29.E.2.b)

To fully meet this indicator:

- The current MDHHS Title X Family Planning Standards and Guidelines Manual must be available to staff at each site. **(18.B)**
- The agency must have written personnel policies that comply with federal and state requirement and Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, and Title I of Americans with Disabilities Act (Public Law 101-336). These policies should include: **(8.5.1)**
  - Staff recruitment and selection
  - Performance evaluation
  - Staff promotion
  - Staff termination
  - Compensation and benefits
  - Grievance procedures
  - Patient confidentiality
  - Duties, responsibilities, and qualifications of each position
  - Licenses for positions requiring licensure
- Personnel records are kept confidential. **(8.5.1.A)**
- Performance evaluations of program staff are conducted according to the agency personnel policy. **(8.5.1.B)**
- Organizational chart and personnel policies are available to all personnel. **(8.5.1.C)**
- Job descriptions are available for all positions and updated as needed. **(8.5.1 D)**
- The agency must have a qualified Family Planning project coordinator. **(8.5.3)**
- All clinicians, including mid-level practitioners, must maintain current licensure and certification, including drug control licenses. **(8.5.4; 29.E.2.b)**
- The agency must have written plans, protocols procedures for non-medical emergency situations, such as fire, tornado, bomb, terrorism, etc. **(13.2, 29. C)**
- The agency provides for orientation and in-service training for all program personnel, including staff of sub-recipient agencies and service sites. **(8.6.1)**
- The agency provides staff training on encouraging family involvement in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities at least every two years. **(8.6.2)**
- The agency provides staff training regarding prevention, transmission and infection control in the health care setting of sexually transmitted infections including HIV as required by OSHA regulations. **(8.6.3)**
- The agency provides staff training in emergency procedures or natural disaster and staff understands their role. **(8.6.4, 13.2, 29.C)**
- The agency provides staff training in the unique social practices, customs, and beliefs of the under-served populations of their service area at least every two years. **(8.6.5)**
- The agency provides staff training on content related to mandated reporting and human trafficking, including information on agency policy and procedures on mandatory reporting at least every two years. **(8.6.6)**
- The agency provides training regarding the nature and safety of pharmaceuticals to clinical staff involved in dispensing medications at least every two years. **(8.6.7; 29.B.2.d; 29.B.4.a)**
- Licensed medical staff providing direct patient care is trained in CPR and have current certification. **(29.C.3; 29.E.2.b)**

Documentation Required:

- Policies and procedures for non-medical emergencies, including fire, natural disaster, robbery, power failure, and harassment.

Section IX: Family Planning

- Agency personnel policies.
- Position descriptions.
- Copies of licenses for those positions requiring licensure.
- Documentation of staff orientation and in-service training, including:
  - Staff training on the unique social practices, customs, and beliefs of the under-served populations in their service area
  - Evidence of staff trained in the prevention, transmission and infection control in the healthcare setting of sexually transmitted infections including HIV
  - Pharmaceutical training for clinical staff involved in dispensing medications
  - CPR training and certification for all licensed medial staff providing direct care
  - Staff training in emergency procedures and plans
  - Staff training on blood born pathogen transmission/OSHA training
  - Staff training on encouraging family involvement in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities
  - Staff training on mandatory reporting and human trafficking, including information on agency policies and procedures.
- Documentation of staff continuing education
- Documentation of performance evaluations as required by agency personnel policy

MPR 3

Provide, to 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. Projects must provide for an advisory committee.

Reference: *42 CFR §59.5 (b)(4); MDHHS Michigan Title X Family Planning Standards & Guidelines; CFR Part 84; 29 CFR Part 1910 Subpart E.*

Indicator 3.1
Opportunity for Community Participation, Advisory Committee

See Michigan Title X Family Planning Standards & Guidelines (11.1; 11.1.A; 11.1A.1,2,3; 11.2)

To fully meet this indicator:

- The agency must provide an opportunity for participation in the development, implementation, and evaluation of the project. **(11.1)**
  - The agency must have a governing board, program specific Family Planning Advisory Council (FPAC) or other appropriate advisory group: **(11.1.A)**
    - The council or board is broadly representative of the population served and includes people knowledgeable about family planning. (**11.1.A.1**)
    - Responsibilities of the council/board must include the following: **(11.1.A.2)**
      - Review the agency's program plan, assess accomplishments and suggest future program goals and objectives.
      - Review the agency's progress toward meeting the needs of the priority population and for making clinic services and policies responsive to the needs of the community.
    - There is documentation that the council/board meets at least once a year. **(11.1.A.2)**

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- Minutes are kept of all meetings **(11.1A.3)**

Documentation Required:

- Governing Board or FPAC Roster
- Governing Board or FPAC meeting schedule
- Governing Board or FPAC meeting minutes

Indicator 3.2

Information and Education (I&E) Advisory Committee

See Michigan Title X Family Planning Standards & Guidelines (12; 12.1; 12.2; 12.3; 12.4.A-H; 12.5)

To fully meet this indicator:

- The agency must have an I & E committee that reviews and approves all informational and educational materials (print or electronic) developed or made available by the project prior to their distribution. (The Family Planning Advisory Committee/Advisory Board may take on this role so long as it meets the following requirements.) (**12; 12.1)**
  - I & E committee membership is broadly representative of the community served, in terms of demographic characteristics of the community for which materials are intended. **(12.2)**
  - The size of I & E committee is at least five members and up to the number determined needed to broadly reflect the community served. **(12.3)**
  - The I & E committee must have a written description of the review and approval process in a policy statement, by-laws or other committee documents. **(12.4.A)**
  - The I & E committee must consider: **(12.4.D)**
    - The educational and cultural backgrounds of the individuals to who the materials are addressed
    - The standards of the population to be served with respect to such materials
    - Review the content to assure the information is medically accurate, culturally/linguistically appropriate, inclusive and trauma-informed.
    - Determine whether the material is suitable for the population or community served.
  - The considerations of materials by I & E committee members must be documented using an approved MDHHS evaluation form. **(12.4.C)**
  - I & E committee approval of educational materials requires at least one half of voting members. **(12.4.E)**
- I & E Committee must meet at least once a year or more often as needed**. (12.4.F)**
- The agency must maintain a written record of the determinations and approval process including: **(12.4.G)**
  - Minutes of all meetings, including a record of determinations regarding the materials reviewed
  - Completed evaluation forms or a compiled summary of the evaluations
  - A master listing of approved materials and dates approved
- Staff overseeing work of the I & E Committee must bring previously approved materials for review and/or update at least every three years. **(12.4.H)**
- Federal grant support must be acknowledged in publications produced with family planning grant funds. **(12.5)**
  - Acknowledgement includes the following language, unless the agency has requested and received a waiver for alternate language from MDHHS: "This [publication/program/website, etc.] was supported by the Office of Population Affairs (OPA) of the U.S. Department, of Health and Human Services (HHS) as part of a financial award totaling $XX with XX percentage funded by OPA/OASH/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by OPA/OASH/HHS, or the U.S. Government. For more information, please visit: https://opa.hhs.gov/."

Documentation Required:

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- I & E Committee Roster indicating community representation of each I & E Committee member
- I & E Committee Meeting Minutes
- I & E determinations related to materials, including individual evaluation forms or a record of individual evaluations
- A Master List of approved materials with dates approved

Evaluation Questions:

- Does the I & E committee review the content of all informational and educational materials to assure the information is correct and appropriate for the intended audience?
- Does the I & E committee membership broadly represent the community served? Does not include program staff and prioritizes client and community representation?
- Does the I & E committee roster indicate community representation for each committee member?
- Is there a written record of the determinations of I & E committee members for all materials reviewed: Meeting minutes; Master list of approved materials with dates approved; Individual evaluation forms, or a compiled summary of member evaluations?
- Is there acknowledgement of Title X grant funding on all publications produced by the project? Does acknowledgement contain the required language and grant award number current at the time of publication?
- Are previously approved materials reviewed or updated at least every three years?

MPR 4

Provide for opportunities for community education, participation, and engagement to achieve community understanding of the objectives of the program; inform the community of the availability of services; and promote participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered quality family planning services.

Reference: *42 CFR §59.5 (b)(3)(i-iii).*

Indicator 4.1

See Michigan Title X Family Planning Standards & Guidelines (4; 5; 8.7. A; 11.2; 11.3)

To fully meet this indicator:

- The agency must establish and implement planned activities to provide community education programs to facilitate awareness and access to family planning services and encourage participation by diverse persons in the communities served. **(11.2: 11.3)**
- The agency must submit an Annual Health Care Plan that includes written plans for: (**4; 5; 8.7.A; 11.2; Section I.B. Annual Health Care Plan Guidance)**
  - Community education activities
  - Community project promotion activities
- The agency must include priority populations based on an assessment of community needs in the target groups identified for program promotion activities. **(11.2,3; 8.7.A)**

Documentation Required:

- Annual Health Care Plan

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- Documentation of community education activities (such as, flyers, community meeting agendas, brochures, reports, logs)
- Documentation of activities program promotion activities (such as Outreach logs, news releases, articles, PSA's, and advertisements)
- Newsletters and other communications/educational tools as available

MPR 5

Provide for billing and collecting client fees to include the following: Clients with family income at or below 100% of the Federal Poverty Level (FPL) are not charged, except where payment will be made by an authorized third party. Charges will be made for services to clients with family income between 101-250% of FPL in accordance with a schedule of discounts based on ability to pay. Charges to clients with family income that exceeds 250% of FPL will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

References: *42 CFR §59.5 (a)(7)-(9).*

Indicator 5.1

See Michigan Title X Family Planning Standards & Guidelines (8.4; 8.4. A-C; 8.4.1; 8.4.2; 8.4.3; 8.4.4; 8.4.5; 8.4.5.B; 8.4.8 A-B; 8.4.9)

To fully meet this indicator:

The local agency must have written policies and procedures for billing and collecting client fees; these policies must include the following:

- Clients must not be denied services or be subjected to any variation in quality of services because of inability to pay. **(8.4)**
- Individual eligibility for a discount must be documented on the client's record/file. **(8.4.A)**
- The agency relies on client self-report of income for determining eligibility for a discount, except where the agency may use income verification data provided by the client because of participation in other programs operated by the agency. **(8.4.B)**
- The agency's schedule of discounts must be developed with sufficient proportional increments to assure billing is based on ability to pay. Sub-recipients must use the mandated quartile proportional increments distributed by MDHHS unless they have requested and received an MDHHS approved waiver to use other proportional increments. **(8.4.C)**
- Clients whose documented income is at or below 100% of the federal poverty level are not charged; although the agency bills all third parties authorized or legally obligated to pay for services. **(8.4.1)**
- For clients with family incomes between 101% and 250% of the current federal poverty level, the agency has a schedule of discounts that is proportional and based on ability to pay. **(8.4.2)**

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- For clients from families whose income exceeds 250% of federal poverty level, the agency has a schedule of fees designed to recover the reasonable cost of providing services **(8.4.4)**
- The agency has a documented process for determining the costs of providing services and indicates how the schedule of fees is determined to recover reasonable costs of providing services. **(8.4.4)**
- Fees are waived for individuals with family incomes above the federal poverty level who, as determined by the site manager, are unable, for good cause, to pay for family planning services. Instances where fees are waived are documented in the client record. **(8.4.3)**
- The agency reviews program costs and reassess the fee schedule at least every two years, utilizing the MDHHS Family Planning Program cost analysis tool unless the agency has a waiver to use a different methodology for reviewing costs. **(8.4.4)**
- The agency charges minors obtaining confidential services based on the resources of the minor and not on the family income. **(8.4.5)**
- The agency does not have a policy or fee schedule that is different for minors than the fee schedule for other populations receiving family planning services. **(8.4.5.B)**
- The agency has the capacity to provide a bill for the services to a client who requests a bill. **(8.4.8.A)**
- The agency's policies on billing and collections include a policy on the "aging" of outstanding accounts. **(8.4.8.B)**
- Voluntary donations from clients are permissible; however, clients are not pressured to make donations and donations are never a prerequisite to provision of services or supplies. **(8.4.9)**

Documentation Required:

- Client records showing eligibility for discount for services
- Billing records
- Proportional sliding fee schedule established using current DHHS Poverty Guidelines
- Written agency policy and procedures for charging, billing, and collecting client fees
- Agency procedure for aging outstanding accounts

Evaluation Questions:

- Are fees waived for individuals with family incomes above the federal poverty level who, as determined by the site director, are unable to pay for services? Is this written in policy? Are incidents where fees are waived for good cause documented in the client record?

MPR 6

Provide that where there is a third party (including a government agency) authorized or legally obligated to pay for services, all reasonable efforts are 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, an agreement required.

Reference: *42 CFR §59.5 (a)(10); 42 CFR §59.5 (a)(8)(I, ii)*

Indicator 6.1

See Michigan Title X Family Planning Standards & Guidelines (8.4.6.; 8.4.6.A; 8.4.7; 8.4.8)

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To fully meet this indicator:

- Where there is legal obligation or authorization for third party reimbursement; all reasonable efforts must be made to obtain third party payment, without application of any discounts. **(8.4.6)**
- With regard to insured clients whose family income is at or below 250% federal poverty level; where deductible, copayments or additional fees apply, clients are never charged more than they would pay if services were charged based on the schedule of discounts. **(8.4.6.A)**
- Where reimbursement is available from Title XIX or Title XX of the Social Security Act, the agency has written agreements/registration with Title XIX, or XX agencies, for reimbursement from these agencies**. (8.4.7)**
- The agency makes reasonable efforts to collect charges without jeopardizing client confidentiality. **(8.4.8)**

Documentation Required:

- Client records showing third party pilling and reimbursement for services
- Written policy and/or procedures for charging, billing, and collecting client fees from third party payers
- Billing for Title XIX, XX, or XXI and receipts of reimbursements

Evaluation Questions:

- Do agency staff follow the billing and client fee collection procedures?

MPR 7

Provide that all services purchased for project participants are authorized by the project director or designee on the project staff. And provide that any family planning services provided by contract or similar arrangements with other service providers, are provided in accordance with a plan which establishes rates and method of payment for 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 §59.5 (b)(7,9).*

Indicator 7.1

See Michigan Title X Family Planning Standards & Guidelines (8.3.2; 8.3.3; 8.3.4; 21.B.7; 29.A.4; 29. B.3.b, c, d.)

To fully meet this indicator:

- All services purchased for project participants must be authorized by the project director or their designee on the project staff (**8.3.3)**
- The agency must have proper segregation between requisition, procuring, receiving, and payment functions for pharmaceuticals and supplies. (**29.B.3.b, c)**
- There must be an inventory system to control purchase, use, and reordering of pharmaceuticals and supplies. **(29.B.3.c, d)**
- Safeguards must be in place to assure that drugs purchased through the 340B program for Title X are only used for clients of the family planning program and in compliance with state and federal laws. **(29.B.3; 29 B.4.d.3)**
- The agency must have in place formal arrangements regarding provision of services and reimbursement of costs for contractual services. **(8.3.2; 8.3.4)**
- If a delegate agency provides required services by referral, formal arrangements with the referral provider must be in place that include a description of the services provided and includes cost reimbursement information. **(8.3.4; 29.A.4; 21.B.7)**

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- If a delegate agency subcontracts for services, a formal agreement must be in place that assures consistency with Title X program requirements, must be identified in the annual plan and must have MDHHS approval. **(8.3.2)**

Documentation Required:

- Policies and procedures
- Records of pharmaceutical requisitions
- Documentation of Inventory system
- Records of equipment purchases over the past three years
- Copies of contractual agreements for family planning services purchased.
- Copies of referral agreements between for providing required services.
- Copies of subcontract agreements

MPR 8

Provide all core family planning services as outlined in *Providing Quality Family Planning Services (QFP): Recommendations of the CDC and U.S. Office of Population Affairs*. These include a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling; assistance to achieve pregnancy; basic infertility services; STI services; preconception health services; and adolescent-friendly health services); and related preventive health services.

References: *42 CFR §59.5(a)(1); 42 CFR CH. 1 §59.5 (b)(1); 42 CFR §59.5 (a)(5); MMWR/ April 25, 2014/Vol 63 /No. 4. Providing Quality Family Planning Services; Recommendations of CDC and the US OPA; MMWR/ July 29, 2016/Vol.65/No.4. US Selected Practice Recommendations for Contraceptive Use, 2016; MMWR/ Centers for Disease Control and Prevention (CDC) Selective Practice Recommendations (SPR); MMWR/July 29, 2016/Vol 65/No.3 US Medical Eligibility Criteria for Contraceptive Use, 2016; MMWR/Vol.70/No.4 Sexually Transmitted Infection Treatment Guidelines, 2021; Michigan Title X Family Planning Standards & Guidelines*

Indicator 8.1

The agency must provide **Contraceptive Services**, including a **broad range of medically (FDA) approved contraceptive products and natural family planning methods and services.**

See Michigan Title X Family Planning Standards & Guidelines (8.2; 8.2A; 8.2.B; 9.8; 18. A, B; 19. B, C; 19.K.1, 2; 19.L, M; 21; 21.A; 21. A, B, C, D, E, F,G; 29.B.7; 29.D.2.c.4)

To fully meet this indicator:

- The agency provides a broad range of medically approved services, including FDA approved contraceptive products and natural family planning methods, and temporary and permanent contraception either on-site or by referral. **(9.8; 18. A)**

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- Written protocols and procedures to offer contraceptive services that are current and consistent with national standards of care, including the QFP, must be in place and available at each clinic site. **(18.B; 21; 21.A)**
- Provide that individual education and counseling is offered prior to the client making an informed choice regarding family planning services. **(19.B.C.)**
- Methods provided and for which written protocols must be in place, include: **(21. B, C, D)**
  - Reversible Contraception
    - Hormonal contraceptives
      - at least 2 delivery methods combined hormonal contraceptives on site
      - at least 1 method progestin-only hormonal contraceptive on site
      - at least a second progestin-only method available on site within 2 weeks
    - Condoms (at least male condoms)
    - At least one type of long acting reversible contraceptive (LARC) method is provided, either on site or by paid referral.
    - At least one type of natural family planning method is provided.
    - Education materials and information regarding all methods including:
      - Hormonal contraceptives
      - Abstinence
      - Fertility awareness-based methods
      - Barrier methods
      - LARCs (Intrauterine devices or Implants)
      - Sterilization
      - Emergency contraception
  - Emergency Contraception
    - Emergency Contraception education and provision or referral are provided as appropriate.
    - A written protocol is in place
  - Permanent Contraception (Sterilization)
    - Education and information regarding sterilization is provided for clients as appropriate.
    - The agency has a list of community providers where clients can be referred for sterilization (Paid referrals for sterilization are not required)
    - All federal regulations on sterilization are met if the procedure is performed by the agency
- The agency does not provide abortion as a method of family planning and has a written policy that no Title X funds are used to provide or promote abortion as a method of family planning. **(8.2; 8.2A)**
    - The agency follows Title X guidance regarding abortion-related services. **(8.2.B)**
- Clients who are undecided on a contraceptive method are informed about all methods that can be safely used based on the CDC MEC. **(21.G)**
- Client education and information about contraceptive methods is medically accurate, balanced, and provided in a nonjudgmental manner. **(21.G)**
- Client education about contraceptive methods that can be safely used includes: (**21.G.1. a-i)**
  - Method effectiveness
  - Correct and consistent use of the method
  - Benefits and Risks
  - Potential side effects
  - Protection from STDs
  - Starting the method
  - Danger signs
  - Availability of emergency contraception
  - Follow-up visits
- Documentation of contraceptive education and counseling must be in the client's medical record**. (21.G.3)**
- An informed consent for the procedure is obtained prior to inserting an IUD or implant. **(21.G.7)**
- Medical records of transfer clients receiving prescriptive methods contain: **(29.B.7)**

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  - A general consent for services
  - A completed client history that has been reviewed
  - A documented blood pressure (BP), if the client desires to continue a combined hormonal method
  - Documentation of the prescription in the client record method
- Medical history elements required for the contraceptive client: **(21.E.1)**
  - Reproductive goals
  - Allergies
  - Medications
  - Immunizations (Michigan Care Improvement Registry "MCIR" is strongly recommended)
  - Menstrual history
  - Gynecologic and Obstetrical history
  - Recent intercourse
  - Recent delivery, miscarriage or termination
  - Contraceptive use
    - Contraceptive experiences and preferences
    - Partner history (use of contraception, pregnant, has children, miscarriage or termination)
    - Condom use, allergies to condoms
    - Interest in Sterilization if age appropriate (≥ 21 per federal law requirement)
  - Current Infectious or chronic health condition (e.g., hypertension)
  - Characteristics and exposures that might affect the client's medical eligibility criteria (MEC) for contraceptive methods. (e.g., age, postpartum, breastfeeding, smoking)
  - Social history/risk behaviors
  - Sexual history and risk assessment
  - Mental health
  - Intimate partner violence
- Taking of a medical history must not be a barrier to making condoms available in the clinical setting **(21.E)**
- The following physical and laboratory assessment are provided for contraceptive clients: **(21.F.1)**
  - For clients seeking combined hormonal method and needing screening for hypertension, the following **must** be provided:
    - Blood Pressure (screen for hypertension)
  - For clients seeking IUD insertion, fitting diaphragm or cervical cap, bimanual exam and cervical inspection **must** be provided.
    - CT and GC testing must be available for clients requesting IUD insertion, if indicated.
  - Pap screening and clinical breast exam **must** be provided based on current recommendations for timing and testing components. (See Related Preventive Health Services section.)
  - Chlamydia testing **must** be offered annually for all females < 25 years, sexually active females ≥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.)
  - For male clients, laboratory tests are not required unless indicated by history.
- Revisits are individualized based on the client's need for education, counseling and clinical care beyond that provided at the visit. **(19.K.1,2; 19.L, M; 29.D.c.4)**

Documentation Required:

- Protocol and procedures manual specific to all contraceptive methods services
- Educational materials for all methods
- Access to clients' records
- Consent forms used for procedures

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Indicator 8.2

Offer **pregnancy testing and counseling services**, including offering pregnant clients the opportunity to be provided information and counseling on options.

See Michigan Title X Family Planning Standards & Guidelines (8.2 A; 9.10; 9.11; 19. K. 1,2; 19.L, M; 24; 24 A-E; 29.D.2.c.4)

To fully meet this indicator:

The agency must:

- Provide pregnancy testing, information and counseling to all clients in need of this service. **(9.10; 24)**
- Have written protocols and procedures to offer pregnancy testing and counseling services that are current and consistent with national standards of care available at each clinic site **(24)**
- Pregnancy diagnosis services include the following: **(24.A)**
    - General consent for services
    - Reproductive Goals discussion
    - Pertinent medical history
    - Environmental risk assessment
    - Testing with highly sensitive pregnancy test
    - Test results given to the client
    - Counseling and referral resources as appropriate
    - Chlamydia testing must be offered to females <25 years of age and as indicated by risk factors for females 25 years old or older
- If a pregnancy test is positive, and if ectopic pregnancy or other pregnancy abnormalities are suspected, immediate referral for diagnosis and treatment must occur. **(24.B.4)**
- The agency offers pregnant clients information and counseling regarding the following options: **(9.10.a,b; 24.C)**
    - Prenatal care and delivery
    - Infant care, foster care or adoption services
    - Pregnancy termination
- When providing pregnancy options information and counseling, the agency provides neutral, factual information and non-directive, unbiased counseling on each of the options and provides referrals upon request, except with respect to any option(s) about which the pregnant client does not wish to receive such information and counseling. **(9.10.c; 24.D)**
- Clients considering or choosing to continue the pregnancy are provided a referral for prenatal care and initial prenatal counseling upon request. **(24.G)**
- Clients considering or choosing to terminate the pregnancy are provided current information about the legal status of abortion in Michigan and are provided a referral upon request.
- For clients with a negative test, appropriate information about family planning services must be offered. **(24.H,I)**
- Revisits are individualized based on the client's need for education, counseling, contraceptive or preventive care, or repeat testing. **(19.K,L,M)**

Documentation Required:

- Protocol and procedures for pregnancy diagnosis and counseling(24.H
- Client medical records
- Educational materials related to pregnancy
- Current referral lists

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Evaluation Questions:

- Are referral lists current and do they include a full range of providers for pregnancy care?
- Is Chlamydia testing incorporated into pregnancy testing visits?

Indicator 8.3

Offer services to clients who desire to **achieve pregnancy**.

See Michigan Title X Family Planning Standards & Guidelines (19.K.1,2; 19.L, M; 23; 23. A, B; 23.D.10; 29.D.2.c.4)

To fully meet this indicator:

- Written protocols and procedures for achieving pregnancy that are current and consistent with national standards of care must be available at each clinic site **(23)**
- Client assessment includes: **(23.A)**
  - Reproductive goals
  - When pregnancy is desired
  - Length of time they have been attempting pregnancy.
    - If less than 1 year, provide counseling on maximizing fertility success
  - History of pregnancies or infertility
  - Partner engagement and support system issues
- Medical history includes: **(23.B)**
  - Immunizations
  - Medications
  - Present infectious or chronic health conditions
  - Genetic conditions
  - Environmental exposures or risks for both partners, (e.g., smoking, alcohol, Zika risk)
  - Social history/risk behaviors
  - Sexual health risk assessment
  - Mental health
  - Reproductive history
    - History of prior pregnancy/birth outcomes (preterm, cesarean delivery, miscarriage, or stillbirth)
    - Past medical/surgical history that might impair reproductive health
    - Medical conditions associated with reproductive failure that could reduce sperm quality
  - Family history
  - Intimate partner violence
- Physical Assessment includes:
  - Height, weight, BMI (screen for obesity)
  - Blood Pressure (screen for hypertension)
  - Physical exam as needed to evaluate issues raised by review of systems or complaints raised by the client.
  - STI or preconception care screening or referral for infertility or other health services as indicated.
- Client education and counseling must be documented in the medical record. **(23.D.10)**
- Revisits are individualized based on the client's need for education, counseling and clinical care beyond that provided at the visit. **(19.K.1,2; 19.L, M; 29.D.c.4)**

Documentation Required:

- Protocol and procedures for achieving pregnancy
- Client medical records
- Educational materials related to achieving pregnancy

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- Current referral list

Indicator 8.4

Offer **basic infertility** services to clients desiring these services. Infertility is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse.

See Michigan Title X Family Planning Standards & Guidelines (19.K.1,2; 19.L, M; 25; 25.C.1,2. a-o; 25.C.3.a-f; 25.D.1,2. a-j; 25.F.1; 29.D.c.4)

To fully meet this indicator:

- The agency offers basic infertility services to clients desiring these services**. (25)**
- Written protocols and procedures to offer basic infertility services are current and consistent with national standards of care. **(25)**
- Evaluation as early as 6 months after regular unprotected intercourse provided for:
  - Female clients >35
  - History of oligo-amenorrhea
  - Known or suspected uterine or tubal disease or endometriosis
  - Partner known to be sub-fertile
- Medical history elements for both clients includes: **(25.C.1,2. a-p)**
  - Reproductive history (methods of contraception, coital frequency and timing, duration of infertility, prior infertility, gonadal toxin exposure, including heat)
  - Past surgeries
  - Previous hospitalizations
  - Serious illnesses or injuries
  - Past infections
  - Medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, diabetes mellites, or other endocrine disorders)
  - Childhood disorders
  - Cervical cancer screening results and any follow-up treatment
  - Medications (prescription and nonprescription)
  - Allergies
  - Social history/risk behaviors
  - Family history of reproductive failures
  - Level of fertility awareness
  - 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
  - Sexual history (pelvic inflammatory disease, history of/exposure to STIs both partners, problems with sexual dysfunction)
  - Review of systems (symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism)
- The following physical examination is offered for both clients if clinically indicated: **(25.C.3.a,b)**
  - Female physical examination:
    - Height, weight, and body mass index (BMI) calculation
    - Thyroid examination (i.e., enlargement, nodule, or tenderness)
    - Clinical breast examination (CBE)
    - Signs of androgen excess
    - 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)
    - STI/HIV testing, as indicated

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- Chlamydia testing must be offered for females < 25 and females ≥ 25 with risk factors.
- Male physical examination:
  - Examination of the penis (including location of the urethral meatus)
  - Palpation of the tests and measurement of their size
  - Presence and consistency of both the vas deferens and epididymis
  - Presence of a varicocele
  - Secondary sex characteristics
  - STI/HIV testing, as indicated
- Revisits are individualized based on the client's need for education, counseling and clinical care beyond that provided at the visit. **(19.K.1,2; 19.L, M; 29.D.c.4)**
  - Clients are referred for further diagnosis and treatment if indicated or requested. **(25.E)**

Documentation Required:

- Protocol and procedure manual
- Infertility educational materials
- Referral provider list

Indicator 8.5

Provide **Sexually Transmitted Infection (STI) Services** to clients desiring these services

See Michigan Title X Family Planning Standards & Guidelines (19.K.1,2; 19.L, M; 21.F.1.d, e; 26; 26.A; 26.B.1-7; 26.C; 26.D.1,2; 26.E; 26.I.1; 29.D.c.4)

To fully meet this indicator:

- Written protocols and procedures to offer STI services that are current and consistent with national standards of care must be available at each clinic site **(26)**
- Medical history elements required for STI services clients include: **(26.A, B.1-6)**
  - Reproductive Goals
  - Allergies
  - Medications
  - Medical conditions
  - Sexual health assessment
  - Intimate partner violence
  - Immunization status
- Physical and Laboratory assessment required for STI services clients include: **(26.C; 26.D.1,2; 26.E; 26.I; 21.F.1.d, e)**
  - Physical exam as indicated based on history or symptoms
  - Chlamydia (CT) and Gonorrhea (GC) testing must be offered annually to clients with risk factors
    - Chlamydia testing must be offered to females <25 years of age and as indicated by risk factors for females 25 years old or older
  - When provided on site, agencies must follow current CDC Guidelines and follow state and local reporting requirements
- Agency complies with state and local STI reporting requirements. **(26. I.1**)
- Revisits are individualized based on the client's need for education, counseling and clinical care beyond that provided at the visit. **(19.K.1,2; 19.L, M; 29.D.c.4)**

Documentation Required:

- Protocol and procedure manuals
- Access to client medical records

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Evaluation Questions:

- Are medical history, physical examination and laboratory screening elements based on the specific services provided to the client?
- Is Chlamydia testing offered annually to females <25 and as indicated by risk factors for women over 25?

Indicator 8.6

Offer **Preconception Health Services** to clients desiring these services

See Michigan Title X Family Planning Standards & Guidelines: **(19.K.1,2; 19.L, M; 22; 22.A, B, C, D; 29.D.c.4**)
.

To fully meet this indicator:

- Written protocols and procedures to offer preconception health services that are current and consistent with national standards of care must be available at each clinic site, **(22)**
- Medical history elements required for preconception health clients: **(22.A. 1-11)**
  - Reproductive goals
  - Sexual health/risk assessment
  - Reproductive history
    - History of prior pregnancy/birth outcomes (e.g., preterm, cesarean delivery, miscarriage, or stillbirth)
    - Past medical/surgical history that might impair reproductive health (e.g., conditions that could reduce sperm quality, varicocele)
  - Environmental exposures, hazards and toxins (smoking, alcohol, other drugs, Zika risk)
  - Medications
  - Genetic conditions
  - Family history
  - Social history/risk behaviors
  - Intimate partner violence
  - Immunizations (MCIR is strongly recommended)
  - Depression
- The following physical and laboratory assessment must be provided for all preconception health clients (**22.C; 22.D)**
  - Height, weight, BMI
  - Blood pressure
  - Laboratory testing must be recommended based on risk assessment
    - Chlamydia testing must be offered to females <25 years of age and as indicated by risk factors for females 25 years old or older
- Revisits are individualized based on the client's need for education, counseling and clinical care beyond that provided at the visit. **(19.K.1,2; 19.L, M; 29.D.c.4)**

Documentation Required:

- Protocol and procedure manual
- Access to client medical records
- Educational materials regarding preconception

Indicator 8.7

Offer **Related Preventive Health Services** to women and men desiring these services

See Michigan Title X Family Planning Standards & Guidelines (28; 28.A, B, C)

To fully meet this indicator:

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- Written protocols and procedures to offer preventive health services that are current and consistent with national standards of care must be available at each clinic site. **(28)**
- Clinics must offer/provide and stress the importance of clinical breast exam (CBE) and cervical cancer screening. **(28.A.1,2)**
  - Agencies must comply with current MDHHS Family Planning Breast and Cervical Cancer Screening Protocol. **(28)**
  - Agencies must participate in the Family Planning/Breast and Cervical Cancer Control Navigation Program (FP/BCCCP) Joint Project for both breast and cervical cancer diagnostic services. **(28)**
- Coordination of care must go through the BCCCNP Coordinator unless other referral/payment arrangements are in place. **(28)**
- Clinics must stress the importance of: **(28.B.1,2)**
  - Screening mammography for women aged 40-64 years as indicated.
  - Screening for women aged 25-64 as appropriate.
- Clinics should conduct a genital examination for young male clients as indicated. **(28.C.1-3)**

Documentation Required:

- Protocol and procedure manuals
- Access to client medical records
- Referral/follow-up logs

Evaluation Questions:

- Are protocols and procedures to offer family planning related preventive health services in place?
- Is the current MDHHS Family Planning Breast and Cervical Cancer Screening protocol in use?

MPR 9

Provide family planning and related preventive health services to minors in an adolescent-friendly manner consistent with Title X legislative mandates.

Reference: *42 CFR §59.5 (a)(1); Legislative mandates in title X appropriations related to services to minors.*

Indicator 9.1

Provide Services for Minor Clients

See: Michigan Title X Family Planning Standards & Guidelines: (8.3.7.C; 9.8; 9.12; 9.12.A, B; 10.1.D; 10.4; 13.5; 13.5.C;17; 19.D.1-5; 21. G; 21.H; 21.H.2; 21.H.3; 21.H.4; 21.H.6)

To fully meet this indicator:

- The agency provides family planning and related preventive health services to minors. **(9; 17)**
- The agency must not require written consent of parents or guardians for the provision of services to minors nor notify parents or guardians before or after a minor has requested and/or received family planning services. **(10.1 D; 19. D.1.a)**
- The agency provides confidential services to minors and has policies and procedures in place to assure compliance with state laws regarding mandated reporting of child abuse, child molestation, sexual abuse, incest and human trafficking. **(8.3.7.C; 9.11.B; 13.5; 10.4; 13.5.C; 19.D.1; 21.H.3)**
- Minor clients who are undecided on a contraceptive method are informed about all methods that can safely be used based on CDC Medical Eligibility Criteria. **(21.G)**
- Comprehensive information is provided to minor clients about how to prevent pregnancy. **(21.H; 19.D.5)**

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- Written protocols and procedures are in place that address counseling for minors, including:
  - Encouraging family participation in the decision of minors to seek family planning services **(9.11.A; 19.D. 2; 21.H.4)**
  - Counseling on how to resist attempts to be coerced into sexual activities **(9.11.A; 19.D.3)**
  - Informing minors that services are confidential, and that in special cases (e.g., child abuse) reporting is required **(19.D.1.b; 21.H.3.a)**
  - Informing Minors of potential for disclosure of confidential information to policyholders where the policyholder is someone other than the client. **(10.2.A; 19.D. c)**
  - Education and counseling are documented in the client record **(21.G; 21.H.6)**
- Confidentiality is never invoked to circumvent reporting requirements for child abuse and neglect. **(9.12.B; 10.4)**

Documentation Required:

- Protocols and procedures that address services and counseling for minors.
- Access to records of minor clients to review documentation
- Educational materials that address contraceptives and services to minors.

Evaluation Questions:

- Are policies and procedures in place to comply with mandatory reporting requirements?
- Are policies/procedures in place to inform minors of potential for disclosure of PHI to policyholders where the policyholder is someone other than the client?

MPR 10

Provide family planning medical services under the direction of a clinical services provider with special training or experience in family planning.

Reference: *42 CFR §59.5 (b)(6)*

Indicator 10.1

Medical direction by a clinical services provider with family planning expertise.

See: Michigan Title X Family Planning Standards & Guidelines: (8.5.4; 8.5.4.A, B; 8.5.5; 8.6.9; 9.6; 18.A, B; 29.A; 29.B.2, 3; 29.E.2.c, e)

To fully meet this indicator:

- The medical director must be a licensed, qualified clinical services provider, with special training or experience in family planning. **(8.5.4)**
  - Where a designated medical director is not specialty trained, OB-GYN or with direct experience providing family planning services to clients, at least 4 hours training specific to family planning or reproductive health every two years is documented. **(8.5.4.A; 8.6.9)**
- 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. **(9.6; 18.A; 29.A)**
- The medical director approves and signs protocols and standing orders annually (within the past 12 months). **(9.6; 18.A, B; 29.E.2.e)**
- Clinicians performing medical functions do so under the protocols and/or standing orders approved by the medical director. **(8.5.5)**
- The medical director directs medical services and participates in quality assurance activities. **(29.E.2.c)**

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- Medical Audits to determine conformity with agency protocols and must be conducted quarterly by the medical director
  - At least 2-3 charts per clinician must be reviewed by the medical director quarterly. **(29.E.2.c)**

Documentation Required:

- Evidence that all mid-level providers have agreed to follow clinic procedures, protocols, and standing orders are signed and approved by the medical director
- Medical director's professional and drug control licenses for each clinic location
- Documentation of quality assurance medical audits
- Approved protocols and standing orders
- Curricula vitae of medical director

Evaluation Questions:

- Are medical audits regularly performed by the medical director to assure conformity with agency protocols on a quarterly basis?
- Is there documentation of medical director training where it is required?

MPR 11

Provide for emergency medical management to address medical emergency situations.

Reference: *29 CFR 1910, subpart E; 42 CFR §59.5 (b)(1)*

Indicator 11.1

Medical Emergency/Situations and Equipment and Supplies.

See Michigan Title X Family Planning Standards & Guidelines (19.J, L; 29.A.5; 29.B.7; 29. C.1, 2, 4)

To fully meet this indicator:

- Emergency arrangements must be available for after hours and weekend care and should be posted. **(19.J, L)**
- There must be protocols and procedures for the following on-site medical emergency situations: **(29.C.1)**
  - Vaso-vagal reactions/Syncope (fainting)
  - Anaphylaxis
  - Cardiac arrest
  - Shock
  - Hemorrhage
  - Respiratory difficulties
- Protocols must be in place for emergencies requiring EMS transport, after hour's management of contraceptive emergencies, and clinic emergencies **(29.C.2)**
- Procedures for maintenance of emergency resuscitative drugs, supplies, and equipment must be in place (**29.C.4)**
- At a minimum each clinical site must have the following: **(29.B.7)**
  - Emergency drugs and supplies for treatment of vaso-vagal reaction
  - Emergency drugs and supplies for treatment of anaphylactic shock
- When a client is referred for emergency clinical care the agency must: **(29.A.5)**
  - Document that the client was advised of the referral and importance of follow-up

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- Document that the client was advised of their responsibility to comply with the referral

Documentation Required:

- Protocol and procedure manual
- Evidence of emergency drug and supply maintenance

MPR 12

Projects must operate in accordance with federal and state law regarding the provision of pharmaceuticals including, security and record keeping for drugs and devices.

Reference: *42 CFR §59.5 (b)(1); PA 368 Sec. 333.17745, 333.17745a, 333.17747.*

Indicator 12.1

Pharmaceuticals/ Prescriptions

See Michigan Title X Family Planning Standards & Guidelines (19.J.1,2; 21.B.6; 21.B.11; 29.B; 29.B.2.a, b, c; 29.B.4.d, e, f; 29.B.5; 29.B.6; 29.B.7; 29.C.1,4)

To fully meet this indicator:

- Agencies must operate in accordance with Federal and State laws relating to security and record keeping for drugs and devices. **(29.B)**
- Inventory, supply, and provision of pharmaceuticals must be conducted in accordance with Michigan state pharmacy laws and profession practice regulations. **(29.B)**
- Prescribing, dispensing or delegating dispensing of prescription medications at clinical service sites must be done by a clinical services provider holding a Drug Control License for each clinic location where the storage and dispensing of pharmaceuticals occur. **(8.5.4.A; 29.B.2)**
- Dispensing prescribers only dispense drugs to their clients, with the exception of dispensing prescriptions for expedited partner therapy (EPT) as authorized under Michigan law. **(29.B.3)**
- All medications dispensed in Title X clinics must be pre-packaged. **(29.B.2.a)**
- All prescriptions dispensed (including samples) must be labeled with the following: **(29.B.2.b)**
  - Name/address of dispensing agency
  - Date of prescription
  - Name of the client
  - Name, strength, quantity of drug dispensed
  - Directions for use, including frequency of use
  - Prescriber name
  - Expiration date
  - Record number
- All clients receive verbal and written instructions for each drug dispensed, including instructions on how to use, danger signs, how to obtain emergency care, return schedule, and follow-up. **(19.J.1,2; 29.B.2.c)**
- Sub-recipients must have adequate controls over access to medications and supplies, including. **(29.B.4.d)**
  - Contraceptive and therapeutic pharmaceuticals must be kept in a secure place, either under direct observation or locked.
  - Access to the pharmaceuticals must be limited to health care professionals responsible for distributing these items.
- Sub-recipient has policies and procedures in place to assure 340B Program compliance: **(29.B.5.a-d)**

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  - Safeguards are in place to assure supplies purchased through 340B are provided only to clients of the family program.
  - Medicaid billing procedures are in place to guard against duplicate discounts.
  - Agency maintains purchase and inventory control records that document compliance with 340B requirements.
  - Agency current 340B certification for each clinical site.
- A current, listing all drugs available for Title X clients, must be maintained and reviewed at least annually that includes: **(29.B.5; 21.B.6)**
  - Methods available on site
  - Methods available on site within two weeks
  - Methods available by paid referral
  - Methods available by unpaid referral
- There must be an adequate supply and variety of drugs and devices to meet client contraceptive needs. **(29.B.6)**
- There must be emergency drugs and supplies for the treatment of vaso-vagal reactions and anaphylactic shock at each site where medical services are provided. **(29.B.7; 29.C.1,4)**
- A system must be in place to monitor expiration dates and ensuring disposal of all expired drugs, including drugs for medical emergencies. **(29.B.4.e; 29.C.4)**
- There must be a system in place for silent notification in case of drug recall. **(29.B.4.f)**
- Writing of prescriptions follows the MDHHS prescription policy including: (**21.B.11; 29.B)**
  - Prescriptions may be written for items on the agency formulary, on the client's insurance plan formulary, or for a client's method of choice when unavailable at the service site. **(21.B.8,11; 29.B)**
  - Accepting a written prescription must not pose a barrier for the client

Documentation Required:

- Protocol and procedure manual.
- Access to client medical records
- Pharmacy logs
- Inventory logs
- Formulary for Pharmaceuticals

MPR 13

Projects must operate in accordance with federal and state law and guidelines regarding the provision of laboratory services related to family planning and preventive health

Reference: *42 CFR §59.5 (b)(1); 29 CFR 1910.1030; 42 CFR 493.*

Indicator 13.1

Laboratory Testing and Follow-up

See Michigan Title X Family Planning Standards & Guidelines (9.6; 9.7; 17; 19.I; 21.F.1.c, d; 24.A; 26; 28; 28.A.2; 29.E.2. f, g, h)

To fully meet this indicator:

- Written laboratory protocols and procedures must be in place that include: **(9.6; 9.7 17; 19. I; 21.F.1.c, d; 24.A; 26; 28; 28.A.2.)**
  - Pregnancy testing must be provided on site

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- Pap testing must be provided on site
- STI and HIV testing, or referral for testing
- Laboratory tests must be provided if indicated for a specific method of contraception

- Laboratory audits to assure quality and CLIA compliance must be in place. **(29.E.2.g)**
- Infection control policies and procedures reflecting current CDC recommendations and OSHA regulations must be in place. **(29.E.2.f)**
- Equipment maintenance and calibration must be documented. **(29.E.2.h)**

Documentation Required:

- Protocol and procedure manual
- Access to client medical records
- Appropriate CLIA certificate
- Laboratory logs
- Equipment maintenance logs

MPR 14

Projects must establish a medical record for all clients who receive clinical services, including pregnancy testing, counseling and emergency contraception. Medical records must comply with Health Insurance Portability & Accountability Act of 1996 (HIPAA) privacy and security standards and document quality care standards.

Reference: *42 CFR §59.5 (b)(1); Health Insurance Portability and Accountability Act of 1996 (HIPAA)*

Indicator 14.1

Medical Records and Quality Assurance System

See Michigan Title X Family Planning Standards & Guidelines (29.D.1.a, b; 29.D.2; 29.E; 29.e.2.d, i)

To fully meet this indicator:

- A medical record is established for all clients who receive a clinical service. **(29.D.1.a)**
- Medical records are: **(29.D.1.b)**
  - Complete, legible and accurate
  - Signed and dated by the clinical health professional making the entry, including name, date, and title, as a permanent part of the record
  - Readily accessible
- Medical records contain the following: (**29.D.2)**
  - Personal data sufficient to identify the client:
    - Name
    - Unique client number
    - Address
    - Phone/How to contact
    - Age
    - Sex
    - Race & Ethnicity (FPAR requirement)
    - Income assessment

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- Allergies
- Medical history, as indicated by service(s) provided
- Physical exam, as indicated by services(s) provided
- Documentation of clinical findings, diagnostic/therapeutic orders, including:
  - Treatments initiated and special instructions
  - Continuing care, referral and follow-up
  - Scheduled revisits
- Documentation of all medical encounters, including telephone encounters
- Documentation of all counseling, education, and social services
- Signed general consent for services
- Contraceptive method chosen by the client

- A quality assurance system must be in place to provide ongoing evaluation of family planning services that includes: (**29. E.)**
  - Chart Audits/Record Monitoring to determine completeness and accuracy of the medical record must be conducted quarterly by the quality assurance committee or identified personnel
    - At least 3% of quarterly caseload, randomly selected are reviewed quarterly **(29.E.2.d)**
  - A process to implement corrective actions when deficiencies are noted must be in place. **(29.E.2.i)**

Documentation Required:

- Service protocol and procedure manuals
- Access to client medical records
- Documentation of Audits and/or Record Monitoring

Evaluation Questions:

- Do medical records contain documentation of all medical encounters: medical history and physical exam appropriate to the service(s) provided; documentation of all clinical findings including laboratory test results and follow-up; treatments initiated and special instructions; referrals and follow-up; and scheduled revisits?
- Are Chart Audits/ Record Monitoring Audits to determine completeness and accuracy of medical records being conducted quarterly by a QA committee member or identified personnel?

MPR 15

Provide for coordination and use of referrals and linkages with primary healthcare providers and other providers of healthcare services, local health and human service departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.
Provide for social services related to family planning, including counseling, referral to other social and medical services agencies, and ancillary services which may be necessary to facilitate clinic attendance.
Provide that referral services as convenient as feasible to promote access to services.

References: *42 CFR §59.5 (b)(8); 42 CFR §59.5 (b)(2)*

Indicator 15.1

Provide for Coordination of referral arrangements for other health care, related social services and counseling

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See Michigan Title X Family Planning Standards & Guidelines (9.5; 9.7; 9.7.A; 17; 19.K; 21.G; 29.A; 29.A.1-6; 29.D.2.c, f)

To fully meet this indicator:

- Projects must provide for referrals to other medical facilities as medically indicated. **(9.5; 17)**
- Provide that referrals and follow-up are provided, as indicated, including: **(19.K; 29.A. 1-5)**
  - Referrals made as result of abnormal physical exam or laboratory findings
  - Paid referrals for required services not provided on site
  - Referrals for services determined to be necessary but beyond the scope of family planning
- Referral and follow up procedures must be sensitive to the client's concerns for confidentiality and privacy. **(29.A.1)**
- Client consent for release of information to providers must be obtained, except as may be necessary to provide care or as required by law. **(29.A.2)**
- The agency must have written protocols/procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings. These protocols must include a system to document referrals and follow up procedures, including: **(29.A.3a.b.c; 29.D.2.c; 29.E.2.a)**
  - A method to identify clients needing follow up
  - A tracking system to document referrals and follow up procedures
  - A method to track follow-up results on necessary referrals
  - Documentation in the client record of contact and follow up
    - Documentation of reasons when follow up was not completed
  - Referral procedures must be sensitive to client confidentiality and privacy concerns.
- For services determined to be necessary but beyond the scope of Family Planning, clients must be referred to other providers for care, the agency must: **(9.5; 9.7.A; 29.A.1,5)**
  - Document that the client was advised of the referral and the importance of follow up
  - Document that the client was advised of their responsibility to comply with the referral
  - Referrals are made to providers conveniently located for clients where feasible.
- Social services related to family planning, including counseling services must be provided either on-site or by referral **(9.4; 9.7; 9.11; 17; 19.C, K; 29.A.6)**
- Counseling must be accurate, balanced, and non-judgmental on the contraceptive methods, STIs and HIV. **(9.11; 21.G)**
- The agency must offer education on HIV and AIDS, risk reduction information and either on-site testing or referral for this service. **(17; 26.G)**
- Counseling and referral services must be in place to address identified intimate partner violence and human trafficking **(9.4. A, B)**
- Counseling must be provided by staff that is sensitive to and able to deal with the cultural and other characteristics of the client population. **(8.5.2)**
- Referral lists for social services agencies and medical referral resources must be current and reviewed annually. **(24.B.7; 29.A.6)**
- The client counseling must be documented in the client's record. **(21.G; 29.D.2.f)**
- Agency must maintain a referral list, updated annually, that include health care providers, local health and human service departments, hospitals, voluntary agencies, and health service projects supported by other federal programs. **(29.A.6)**

Documentation Required:

- Protocol/procedure for counseling and referring to other health care, local health and human service departments, hospitals, voluntary agencies or health services projects
- Current referral list, updated annually
- Documentation of referrals and follow-up
- Client medical records with counseling documentation

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Evaluation Questions:

- Are counseling services provided based on the individual client needs/request for services?