

## 15.1 GENERAL CLINICAL INFORMATION

**Policy:** The Montana Family Planning Program (FPP) strives to provide high quality reproductive and preventive health care to its clients.

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

The MT Title X Family Planning Clinical Protocol Manual serves as a companion manual to the MT Title X Family Planning Administrative Manual and provides local programs with clinical protocols for the implementation of Title X services. These protocol manuals are based on the Title X Program Requirements, QFP, requirements of the Montana Department of Public Health and Human Services (DPHHS) FPP, relevant federal and state statutes, and professional medical organizations. The protocols contained in the MT Title X Family Planning Clinical Protocol Manual are minimum medical standards and must be incorporated into each Title X clinic's plan for medical care.

**Quality Title X family planning** care includes the following attributes:

1. Confidentiality
2. Safety
3. Effectiveness
4. Client-centered approach
5. Timeliness
6. Efficiency
7. Accessibility
8. Equity and value

### Procedure

1. All Title X clinics must follow policies and protocols of both the MT Title X Family Planning Administrative Manual and the MT Title X Family Planning Clinical Protocol Manual.
  - a. The MT Title X Family Planning Clinical Protocol Manual must be reviewed and signed by the Medical Director with each revision to the manual.
  - b. The MT Title X Family Planning Clinical Protocol Manual must be initialed and signed by staff involved in client care to indicate that the protocols and policies have been reviewed and adopted.
  - c. Title X clinical staff must use best clinical judgement and must follow their scope of practice and state rules and regulations for licensure requirements.
2. Title X providers must offer all family planning services to female and male clients, including adolescents, as described in the MT Title X Family Planning Administrative Manual, Policy 2.14 *Determining Need for Services*. Other related or other preventive health services that are beyond the scope of Title X may be offered either on-site or by referral.
3. All Title X clinics must provide for medical services related to family planning and the effective use of contraceptive devices and practices including provider's consultation, examination, prescription, 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.
4. Title X providers must be trained and equipped to offer all family planning and related preventive health services so that they can provide optimal care to clients, with referral to specialty care as needed.

5. All Title X clinics must provide clinical services in compliance with applicable federal and state laws. This includes, but is not limited to, Occupational Safety and Health Act (OSHA) standards, Clinic Laboratory Improvement Amendments (CLIA) '88, Montana HB 239 - Infectious Waste Management, and *MCA 37-2-104 Dispensing of drugs by medical practitioners unlawful--exceptions*. OSHA regulations apply to federal and private entities but not to state and local governments in their role as employers. However, private non-profit organizations are bound by these rules. All programs are strongly encouraged to follow OSHA standards.
6. The clinical care component of the Title X clinic must operate under the responsibility of a medical director who is a licensed and qualified physician with special training or experience in family planning (see MT Title X Family Planning Administrative Manual, Policy 4.1 *Title X Personnel*).

### **Informed Consent**

1. Documentation of informed consent must be included in the client's medical record for all clinical services.
2. Title X clients must understand the risk and benefits for clinical services provided.
3. Elements of full informed consent include:
  - a. The nature of the decision/procedure
  - b. Reasonable alternatives to the proposed intervention
  - c. The relevant risks, benefits, and uncertainties related to each alternative
  - d. Assessment of client understanding
  - e. The acceptance of the intervention by the client
4. Informed consent forms must be signed, witnessed and dated before the initiation of any clinical services and become a permanent part of the client's medical record.