MDHHS Family Planning Pharmacy Training

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MDHHS
Michigan Department of Health & Human Services

Why is this pharmacy training required?

- The Title X Family Planning Program, established by Congress in 1970, is the only federal program dedicated solely to providing family planning and related health services to all who chose them.
- For more than 50 years, family planning clinics have been a critical part of the public health safety net, providing a broad range of medically approved family planning services, including Food and Drug Administration (FDA) approved contraceptive products and natural family planning methods.
- Title X clinics are unique in that low-income and underserved people can confidentially obtain their contraceptive method of choice directly from their local family planning clinic.
- Safely dispensing contraceptive supplies and other needed pharmaceuticals along with related health services is essential to providing Title X services.

Why is this pharmacy training required?

- The purpose of this pharmacy training is to outline requirements that pertain to safely dispensing pharmaceuticals in family planning clinics without an onsite pharmacy.
  - A summary of federal laws and regulation governing the approval, classification and labeling of pharmaceuticals dispensed in the United States.
  - A summary of licensing and dispensing laws and regulations that are the responsibility of state authorities.
  - A summary of Michigan laws that govern dispensing pharmaceuticals in clinic settings without an onsite pharmacy such as Title X Family Planning clinics.
  - A summary of Title X requirements regarding provision of pharmaceuticals.

What federal regulations relate to dispensing pharmaceuticals?

- The Food and Drug Administration (FDA) has responsibility for setting federal safety standards for drugs distributed within the United States.
  - National Institute of Health (NIH) summary of FDA's authority and role.
  - The FDA approves all prescription medications including the classification of medications based on safety for dispensing within the United States.
    1. Defines all medications:
       1) Prescription medications.
       2) Over the counter (OTC) medications.
       3) Categorizes controlled substances (Schedule I-V drugs).
       4) Defines manufacturer labeling requirements for each approved drug such as the name of product, drug facts, active and inactive ingredients, use and purpose, warnings, directions and allergic reactions.
    2. Sets standards for ongoing monitoring of drug safety by pharmaceutical manufacturers.

What federal regulations relate to dispensing pharmaceuticals?

- Summary of FDA's authority and role *continued*:
    3. Sets safety standards for storing and distribution records for dispensing of pharmaceuticals.
        1) Title 21 Code of Federal Regulations (CFR) 205.50 defines the minimum requirements for storage and handling of prescription drugs and the establishment and maintenance of drug distribution records.
        2) Title 21 directs the states to develop licensing laws that include these minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors.

What federal regulations relate to dispensing pharmaceuticals?

- Summary of FDA's authority and role *continued*:
    4. Under FDA authority the Drug Enforcement Administration (DEA) regulates controlled substances following the Controlled Substance Act (CSA).
        1) Regulates manufacture, importation, possession, use and distribution.
        2) Categorizes controlled substances (Schedule I-V drugs).

What federal regulations relate to dispensing pharmaceuticals?

- Summary of FDA's authority and role *continued*:
  5. Under FDA guidance the Poison Prevention and Packaging Act of 1970 (PPPA) establishes safety precautions for dispensing medications to protect children under five years of age from accidental poisoning.
     - The Consumer Product Safety Commission (CPSC) was established under PPPA to monitor use of safety packaging and safety labeling required for all medications dispensed within United States.
     - These safety requirements apply to pharmaceuticals dispensed at pharmacies and at clinical settings without an onsite pharmacy, such as family planning clinics.

What state responsibilities relate to dispensing pharmaceuticals?

- Under the Title 21 requirements, specific laws and regulations for handling and dispensing prescription drugs fall under state regulation rather than federal regulations:
  - Professional licensing laws govern **prescriptive authority.**
    - Prescriptive authority is the ability of health care providers to prescribe and dispense legal drugs and controlled substances.
  - **Development of licensing laws.**
    - Licensing laws oversee the storage, handling and dispensing of prescription drugs by pharmacies and by clinical sites within Michigan.
  - **Education and counseling** required with the dispensing of prescription drugs for local pharmacies and for clinical settings that do not have pharmacies.

Michigan Laws Governing Pharmaceuticals

- **Michigan prescriptive authority laws.**
  - **Physicians,** Doctors of Medicine (MDs) and Doctors of Osteopathic Medicine (DOs), have full prescriptive authority under Michigan law.
    - This includes controlled substances, if the MD or DO is licensed and DEA registered.
  - **Advanced Practice Registered Nurses** (nurse practitioners, nurse-midwives, clinical nurse specialists) under Michigan Compiled Laws (MCL) 333.17211a, have the authority to prescribe non-controlled substance prescriptions.
    - With a physician delegation can prescribe controlled substances.

Michigan Laws Governing Pharmaceuticals

- **Michigan prescriptive authority laws.**
  - **Physician Assistants** under MCL 333.17548, have the authority to prescribe medications under a practice agreement with a supervising physician, which may include controlled substances.
  - **Pharmacists** have authority to prescribe certain immunizations and laboratory testing and self-administered hormonal contraceptives under MCL 333.17707g of 2024.
  - All prescribers are required to **electronically transmit prescriptions** for controlled and non-controlled prescriptions, with some exceptions (MCL 333.17754a).
  - **Other prescribers** in Michigan include licensed dentists, optometrists, podiatrists and veterinarians.

Michigan Laws Governing Pharmaceuticals

- **Summary of Michigan's Drug Control Law for dispensing pharmaceuticals in clinical settings.**
  - **Michigan pharmacies** dispense prescription drugs following the Michigan Public Health Code, part 177 which regulates licensing, pharmacy practice, drug control and dispensing.
  - **Clinical settings without an on-site pharmacy** must follow **Michigan's Drug Control Law** (MCH 333.17745) which regulates the storage and dispensing of prescription medications in the clinic setting.

Michigan Laws Governing Pharmaceuticals

- **Summary of Michigan's Drug Control Law for dispensing pharmaceuticals in clinical settings**, *continued*.

1. Michigan's Drug Control Law requires **prescribing providers** to obtain a **drug control license** for **each clinical location** where prescription drugs are stored and dispensed.
   - Each prescribing provider in a dispensing practice must obtain a drug control license for each clinical location where prescription drugs are stored and dispensed.
   - The Michigan Drug Control Licensing Guide provides guidance for applying for and renewing drug control licenses.
   - **Exceptions**: drug control licenses are not required for:
     1. Providers who only dispense complimentary starter dose drugs.
     2. Dispensing in an emergency department, emergency room or trauma center of a licensed hospital.
2. Requires that drugs may only be dispensed to patients of the provider's practice.
   - **Exception:** certain drugs may be dispensed to sexual partners of patients under Michigan's Expedited Partner Therapy (EPT) law (MCL 333.5110).

Michigan Laws Governing Pharmaceuticals

- **Summary of Michigan's Drug Control Law for dispensing pharmaceuticals in clinical settings,** *continued.*

3. Describes requirements for **documenting prescriptions and dispensing in the patient's record.**
    - Prescription drug names, dosages and quantities must be documented in the patient record.
    - Documentation must indicate if prescription is dispensed or prescribed for the patient.
    - If dispensed under prescriber's delegatory authority, the delegatee who dispenses the drugs must initial the patient's record.
4. Describes requirements for **storage and dispensing of pharmaceuticals.**
    - Prescription drugs must be stored in secured, stable conditions and limited to individuals authorized to dispense.
    - Prescriptions drugs must be dispensed in safe containers complying with the PPPA.

Michigan Laws Governing Pharmaceuticals

- **Summary of Michigan's Drug Control Law for dispensing pharmaceuticals in clinical settings,** *continued.*
  5. Describes requirements for the **labeling of dispensed pharmaceuticals.**
     - Drugs must be dispensed in a container that bears a label containing:
       1) Name and address of the location where prescription is dispensed.
       2) Patient's name and record number, except as otherwise authorized for EPT.
       3) Date the prescription drug was dispensed.
       4) Prescriber's name or, if dispensed under the prescriber's delegatory authority, the name of the delegate.
       5) Directions for use.
       6) Name and strength of the prescription drug.
       7) Quantity dispensed.
       8) Expiration date of the prescription drug or the required one-year statement.

Michigan Laws Governing Pharmaceuticals

- **Summary of Michigan's Drug Control Law for dispensing pharmaceuticals in clinical settings,** *continued.*
  6. Describes **delegatory authority for dispensing pharmaceuticals** in the clinical setting.

Title X Pharmaceutical Requirements

- Title X Projects are required to provide medical services related to family planning, including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies … and provide for the effective usage of contraceptive devices and practices (42 CFR §59.5 (b)(1)).
- Title X Projects must offer a broad range of acceptable and effective family planning methods and services, including natural family planning methods, infertility services and services for adolescents (Title X Statute, section 1001; 42 CFR §59.5 (a)(1)).
- The MDHHS Title X Standards & Guidelines identifies essential federal and state legal and safety procedures in Clinical Section III, section 29.B Pharmaceuticals.
- Michigan's Title X Program requires that clinical staff involved in dispensing medications be trained on required legal and safety procedures regarding dispensing pharmaceuticals within the clinic setting at least every **two** years (MDHHS Title X Standards & Guidelines section 8.6.8).

Title X Pharmaceutical Requirements

- The MDHHS Title X Standards & Guidelines identifies essential federal and state legal and safety procedures and Title X requirements in Clinical Section III, section 29.B Pharmaceuticals.
  - It is essential that each service site maintain an adequate supply and variety of drugs and devices to effectively manage the contraceptive needs of its clients (S&G 29.B).
  - 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 Title X (S&G 29.B).
  - The medical director of each Title X family planning project is responsible for all policies and procedures pertaining to the general handling of pharmaceuticals (S&G 29.B.1).
  - Written protocols and operating procedures for the distribution, security and record keeping of pharmaceuticals and supplies must be in place (Minimum Program Requirements (MPR) 10; S&G 29.B.1).

Title X Pharmaceutical Requirements

- Prescription of pharmaceuticals is done by a clinical services provider under the direction of the program's designated medical director (Clinical Section III.29.B.2).
- The prescribing provider may dispense directly or indirectly under their delegated authority to a registered nurse or other appropriately trained service provider. Pre-labeled, pre-packaged oral contraceptives may be distributed if delegated by a dispensing prescriber (Standards & Guidelines (S&G), 29.B.2).
- All medications dispensed in Title X clinics must be pre-packaged (S&G, 29.B.2.a).
- An adequate supply and variety of drugs and devices must be available to meet client's contraceptive needs (S&G, 29.B.7.).
- 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 (S&G, 29.B.6.).
- The agency formulary must contain at least the minimum broad range of contraceptive methods and supplies described in the MDHHS Standards and Guidelines (S&G, 21.B.1-12).

Title X Pharmaceutical Requirements

- MDHHS requires agencies have a minimum of the following methods on site:
  - At least two delivery methods of combined hormonal contraceptives.
  - At least one delivery method of progestin only contraceptive.
  - External male condoms (S&G 21.B.1.a.b & 21.B.2).
- MDHHS also requires agencies have at a minimum:
  - At least a second type of progestin-only method available on site within two weeks of request (S&G, 21.B.1.c).
  - At least one type of long-acting reversible contraceptive (LARC) available on site or by paid referral (S&G, 21.B.3).
  - At least one natural family planning method provided on site (S&G, 21.B.4).
- Agencies are strongly encouraged to regularly review current practice, needs and preferences of clients and maintain their most frequently requested contraceptive methods (S&G, 21.B.9).
- Agencies are strongly encouraged to provide emergency contraception and maintain adequate supplies on site (S&G, 21.B.10).

Title X Pharmaceutical Requirements

- The purchase and use of generic drugs based on therapeutic equivalence as published by the FDA or in the Formularies of Therapeutic Equivalences and accepted by the State Board of Pharmacy is acceptable (S&G, 29.B.7.a).
- Title X projects may elect to identify certain supplies on their formulary, such as their more expensive or infrequently used methods, that will be ordered upon client request and be available within two weeks of that request (S&G, 29.B.7.b).
- Prescriptions may be written for clients who choose and can conveniently obtain their method of choice and medications from a pharmacy (S&G, 29.B).
- Accepting a prescription should not pose a barrier for the client. Clients should be made aware they are responsible for out-of-pocket costs at a pharmacy (S&G 29.B).
- A prescription or referral must be offered for clients whose method of choice is not available at the service site (42 CFR §59.5(1)(a)).

Title X Pharmaceutical Requirements

- **Emergency supplies**
  - At a minimum, each Title X site that provides medical services must have the following emergency supplies (S&G, 29.B.8):
    - Emergency drugs and supplies for treatment of vaso-vagal reaction (S&G, 29.B.8.a).
    - Emergency drugs and supplies for treatment of anaphylactic shock (S&G, 29.B.8.b).
    - Emergency protocols and procedures must be in place (S&G, 29.C).

Title X Pharmaceutical Requirements

- **Inventory**
  - The inventory, supply and provision of pharmaceuticals may be delegated to appropriate qualified health professionals (S&G, 29.B.4).
    - Family planning health professionals delegated to deliver prescriptions drugs must be trained in all aspects of pharmaceutical and supply distribution (S&G, 29.B.4.a).
    - Title X agencies must have proper segregation between requisition, procuring, receiving and payment functions for pharmaceuticals and supplies (S&G, 29.B.4.b).
    - Title X agencies must have an inventory system to control the purchase, use and reordering of pharmaceuticals and supplies (S&G, 29.B.4.c).

Title X Pharmaceutical Requirements

- **Inventory**
  - Title X agencies must have adequate controls over access to medications and supplies including (S&G, 29.B.4.d):
    - Contraceptive and therapeutic pharmaceuticals must be kept in a secure place, either under direct observation or locked (S&G, 29.B.4.d.2).
    - Access to pharmaceuticals must be limited to health care professionals responsible for distributing (S&G, 29.B.4.d.2).
  - A system must be in place to monitor the expiration date on drugs and ensure disposal of all expired drugs (S&G, 29.B.4.e).
  - A system for silent notification in case of drug recall must be in place (S&G, 29.B.4.f).
  - Inventory levels should not exceed a six-month supply (S&G, 29.B.4.g).

Title X Pharmaceutical Requirements

- **Inventory**
  - Title X agencies purchasing supplies through the **340B Purchasing Program** must have policies and procedures in place to assure 340B Program compliance (S&G, 29.B.5):
    - Agencies must assure supplies purchased through the Title X 340B program are provided only to clients of the family planning program (S&G, 29.B.5.a).
    - Michigan Medicaid requires 340B entities to bill Medicaid for 340B purchased supplies at the 340B acquisition price to guard against duplicate discounts (S&G, 29.B.5.b).
    - Agencies must have purchase and inventory control records that comply with 340B requirements (S&G, 29.B.5.c).
    - Agencies must maintain current 340B certification for each Title X clinical service site (S&G, 29.B.5.d).

Resources

- NIH Federal Regulation of Medication Dispensing.
- Title 21 CFR 205.50.
- Controlled Substance Act (CSA).
- Poison Prevention and Packaging Act of 1970 (PPPA).
- 340B Prime Vendor Program.
- Michigan's Drug Control Law.
- LARA's Michigan Drug Control Licensing Guide.
- FDA Drug Topics Webinar: Navigating FDA's Drug Information Resources.
- Michigan's Electronic Transmission of Prescriptions Law.
- Michigan's Expedited Partner Therapy (EPT) Law.
- Michigan Laws that Extend Prescription Authority Beyond Physicians:
  - Advanced Practice Nurses.
  - Physician Assistants.
  - Pharmacists.