



Curriculum for Registered Nurses Preparing and Dispensing Medications and Devices in Local Health Departments 2024

Maryland Department of Health



Introduction and Course Overview



Maryland Department of Health (MDH)'s Online Registered Nurse Dispensing Training

- This course is divided into modules, which are organized to provide the user with a meaningful and flexible learning experience.
- Each module contains information about the various aspects of the dispensing process. Along with content, there are practice questions, helpful links, and other resources.
- The modules are color coded by section as shown on Slide #6 to help you navigate through the course and support self-paced learning. You may exit the course after a module is completed and return to the next module at another time. The course does not have to be completed in one session, however the modules do have to be completed in sequence.
- The post-test is the final section designed to confirm your understanding and readiness to dispense medications and devices in a Local Health Department (LHD).



Course Objectives

At the completion of this course the Local Health Department Registered Nurse (LHD RN) will be able to:

- 1. Define key terms related to the dispensing process
- 2. Demonstrate knowledge of the dispensing process and understand the requirements of the statute
- 3. Identify the agencies involved in supporting the LHD RN dispensing process
- 4. Explain the roles and responsibilities of the LHD RN in the dispensing process
- 5. Identify considerations in dispensing opioids and "Expedited Partner Therapy"
- 6. Apply the Code of Ethics to the dispensing process
- 7. Identify the procedures for managing medication storage, inventory, recall and expired medications and devices

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Course Overview

- There are nine (9) modules. The first seven (7) are content modules, Module 8 provides reference links which include instructions for accessing the <u>MDH Approved Formulary</u>, and Module 9 is the post-test.
- The post-test which follows the modules must be completed with a mandatory passing grade of 90% or higher. If a passing grade is not achieved, the post test can be retaken in 48 hours.
- The curriculum and post test must be completed annually.
- LHD RNs may not dispense medications or devices without completing the entire curriculum and successfully passing the post-test. It is also recommended that LHD RNs be familiar with the Nurse Practice Act in its entirety.
- This curriculum is intended for RNs only, as dispensing is not within the scope of practice for a Licensed Practical Nurse.



Course Model

Introduction and Course Overview	Module 1 Background	Module 2 The LHD RN's Role & Responsibilities	Module 3 Medication/Device Management
Module 4 Strategies for Safe Dispensing	Module 5 Steps in the Dispensing Process	Module 6 Treatment of Substance Use Disorder	Module 7 Expedited Partner Therapy
	Module 8 Formulary and Helpful Links	Module 9 Post-Test	



Modules and Content

- Module 1- Background
- Module 2- The LHD RN's Role & Responsibilities
- Module 3- Medication/Device Management
- Module 4- Strategies for Safe Dispensing
- Module 5- Steps in the Dispensing Process
- Module 6- Treatment of Substance Use Disorder
- Module 7- Expedited Partner Therapy
- Module 8- <u>Formulary</u> and Helpful Links
- Module 9- Post-Test



MODULE 1

Background



Module 1 Content:

- The legal authority and statutory requirements that allow LHD RNs to dispense medications and devices in a LHD
- The definitions as indicated in the statute
- The statutory limitations of nurse dispensing
- The regulatory authority for LHD RN dispensing
- The responsibilities of each party within the regulatory authority



Module 1 Objectives:

By the end of Module 1 the learner will be able to:

- 1. Identify the statutory authority permitting RNs to dispense medications and devices in a LHD
- 2. Understand the meaning of the statutory language used in the Maryland Nurse Practice Act (NPA) that permits LHD RNs to dispense
- 3. Identify the limitations of the authority to dispense
- 4. Identify the regulatory authorities involved in the development and adoption of RN dispensing in a LHD



Applicable Legal Authorities

- In April of 2015, Governor Hogan signed into law a bill giving RNs in LHDs the authority, within the NPA, to dispense medications and devices, subject to the stipulations of the statute. Prior to the passing of this bill, this authority was granted through a declaratory ruling by the Maryland Board of Physicians.
- The Maryland statutes authorizing RNs to dispense medications and devices in a LHD can be found in the Annotated Code of Maryland:
- 2019 Health Occupations §8-512 "Requirements for Registered Nurses to Personally Prepare and Dispense Drugs and Devices in Local Health Departments," and
- 2015 Health General §§ <u>3-401 405</u> "Registered Nurses Personally Preparing and Dispensing Drugs and Devices in Local Health Departments."



Definitions in the Statute

- The following terms (found in Health General §§ 3-401 -405) will be used throughout this curriculum and have the meanings indicated:
- "<u>Authorized prescriber</u>"... an individual authorized by law to prescribe prescription or nonprescription medications or devices.
- "<u>Committee</u>" the committee on Registered Nurses personally preparing and dispensing medications and devices in Local Health Departments.
- "<u>Device</u>" an item used in the diagnosis, treatment, or prevention of disease. A device does not include: surgical or dental instruments, physical therapy equipment, x-ray apparatus, or any parts of the above.
- "<u>Dispense</u>" a procedure that results in the receipt of a medication or device by a patient or a patient's agent and includes: interpreting an authorized prescriber's prescription for a medication or device; selecting and labeling the medication or device prescribed; measuring and packaging the medication or device in accordance with State and federal law; and documenting the transaction in the patient's medical record.



Definitions in the Statute (continued)

- "<u>Drug</u>" a prescription or non-prescription medication
- "<u>Formulary</u>" a list of medications and devices
- <u>"Nonprescription drug</u>" a medication that may be sold without a prescription and is labeled for use by a consumer in accordance with State and federal law
- <u>*"Personally prepare and dispense"*</u> means:
 - physically prepare a prescription
 - perform a final check of the prescription before dispensing it to a patient
 - and not delegate any step of the dispensing process
 - "<u>Prescription Drug</u>" a medication that may be dispensed only on the prescription of an authorized prescriber



Definitions in the Statute (continued)

- "<u>Registered Nurse</u>" means an individual who:
- Is licensed by the State Board of Nursing to practice registered nursing under Title 8 of the Health Occupations Article; and
- Personally prepares and dispenses medications and devices in a LHD:
 - In accordance with the Overdose Response Program under <u>Health General §13- 3101-3111</u>, or
 - In accordance with Expedited Partner Therapy, as authorized in <u>Health General §18-214.1</u>. (Both of these topics will be covered in Modules 6 and 7 respectively), or
 - To patients in need of communicable disease, alcohol and substance misuse, family planning or sexual and reproductive health services

A registered nurse must comply with:

- The <u>formulary</u> developed and approved by the "Committee" and
- The requirements of <u>Health Occupations § 8–512</u> (the NPA)



Difference Between Dispensing and Administering

Dispensing

The preparation, packaging, labeling and transfer of a medication to a patient or an intermediary who is responsible for future administration of the medication

<u>Administering</u>

The giving of a therapeutic agent to a patient by direct application, (e.g., by infusion, inhalation, injection, paste, suppository or oral ingestion)



Scope of Nurse Dispensing

Only an LHD RN can dispense: Health Occupations §8-512 (NPA)

- Medications and devices that are included in the approved MDH <u>formulary</u>
- To patients in need of communicable disease, alcohol and substance misuse, family planning or sexual and reproductive health services, and in accordance with the Overdose Response Program and Expedited Partner Therapy
- A prescription received from an authorized prescriber employed at a LHD
- An over-the-counter oral contraceptive or device, for which a written
 prescription is not required as per Senate Bill 944
 (<u>https://mgaleg.maryland.gov/2024RS/bills/sb/sb0944e.pdf</u>)- LHDs are
 responsible for developing policies and procedures for dispensing over-thecounter oral contraceptives and devices.
- After successful completion of this training program, which is reviewed and updated annually, with a passing post test grade of 90% or higher; and must:
 - Maintain the patient's health record in accordance with State and federal laws and
 - Comply with medication and device storage and inventory procedures in accordance with MDH policy
 Maryland

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Regulatory Authority for Nurse Dispensing

<u>Senate Bill 626 (2015)</u> enacted as <u>Chapter 44</u>, <u>Legislative Acts of 2015</u>, established the Nurse Dispensing Committee. The Nurse Dispensing Committee consists of the following members:

- A representative of MDH, appointed by MDH;
- A representative of the State Board of Nursing (MBON), appointed by MBON;
- A representative of the State Board of Pharmacy, appointed by the State Board of Pharmacy;
- A representative of the State Board of Physicians, appointed by the State Board of Physicians;
- A pharmacist who practices in the State, appointed by the State Board of Pharmacy;
- A RN who practices in the State, appointed by MBON;
- A representative of the Office of Controlled Substances Administration (OCSA**), appointed by OCSA; and
- A representative of a LHD, appointed by MDH.



**previously known as the Division of Drug Control

Regulatory Authority: Roles & Responsibilities

The Committee is responsible for:

Developing and approving a formulary for use by Registered Nurses; and annually reviewing the formulary to ensure compliance with current prescribing standards

The Maryland Department of Health (MDH) is responsible for:

Establishing and administering a training program (the one you are currently taking) for Registered Nurses that has been jointly developed and is annually reviewed by:

- MDH
- The State Board of Nursing
- The State Board of Pharmacy

The LHD employing Registered Nurses is required to:

- Submit to inspection by MDH
- Complete the formulary request form when requesting additions to the formulary
- Provide their RNs access to the training program



Module 1 Self Assessment Questions

Read each question and select the best answer. Correct answers and rationale are provided on the next slide.

- 1. Who is accountable for safe dispensing in the LHD?
 - A) The Board of Nursing
 - **B)** The Board of Pharmacy
 - C) The Board of Physicians
 - D) The LHD dispensing RN
- 2. LHD RNs who have successfully completed this training and have met the requirements outlined in Health Occupations §8-512 can dispense in which of the following:
 - A) STI Clinic
 - **B)** Family Planning Clinic
 - C) Latent Tuberculosis Infection (LTBI) Clinic
 - D) All of the above.
- 3. Providing an IM injection in an Immunization Clinic is an example of nurse dispensing.

True

False



Module 1 Self-Assessment Answers & Rationale

- 1. The correct answer is D) The LHD dispensing RN. The Board of Nursing, the Board of Physicians and the Board of Pharmacy jointly develop the training program for Registered Nurses working in LHDs and participate in annual review of the program to ensure compliance with current prescribing standards. LHD RN's are granted their current authority to dispense through Senate Bill 626, signed into law in April 2015. It is a part of the NPA.
- 2. The correct answer is D) All of the above. -RNs in LHDs who comply with the provisions of the law can dispense to patients in need of communicable disease, alcohol and substance misuse, family planning and, reproductive health services.
- **3.** The correct answer is False. Providing an IM injection is an example of *administering* a medication not dispensing a medication.



Module 2

The LHD RN's Role & Responsibilities



Module 2 Content:

- Ethical obligations and the nurse dispensing process
- Explanation of the role and responsibilities of the LHD RN within the dispensing process
- The application of nursing judgment within the dispensing process



Module 2 Objectives

By the end of Module 2 the learner will be able to:

- 1. Explain the role and responsibilities of the LHD RN in dispensing
- 2. Incorporate the responsibilities of the LHD RN into the practice of dispensing
- 3. Describe how the LHD RN's responsibilities relate to Maryland statutes and regulations
- 4. Apply nursing ethics in the dispensing process
- 5. Use evidence based resources throughout the dispensing process



"What nursing brings to the future is a steadfast commitment to patient care, improved safety and quality, and better outcomes. We believe nurses have key roles to play as team members and leaders for a reformed and better-integrated, patientcentered health care system" (IOM, 2008).





Ethical Responsibilities

The RN is ethically responsible for:

- Providing services unrestricted by consideration of clients' cultural, economic, religious or health status
- Ensuring a client's right to confidentiality
- Protecting a client from incompetent, unethical, or illegal practices from any staff member
- Assuming responsibility and accountability for individual nursing judgments and actions
- Exercising informed judgment
- Maintaining competence in nursing practice
- Promptly report a breach of confidentiality
- Inform the Board of Nursing regarding ethical conduct



COMAR 10.27.19.02

Responsibilities of the LHD RN

- LHD RNs will dispense medications and devices only to clients in need of communicable disease, alcohol and substance misuse, family planning, or reproductive health services who have a written prescription by an authorized prescriber within the LHD. The dispensing RN is responsible for reviewing both pharmaceutical and therapeutic appropriateness of the prescription and will:
 - Review the provider order/prescription
 - Verify the medication or device is on the approved MDH <u>formulary</u>
 - Review the patient's medication history, and other pertinent information
 - Identify possible medication to medication interactions, allergies and/or contraindications
 - Understand the need for the medication or device
 - Use evidence based resources to support decision making throughout the steps involved in the dispensing process
 - Determine the patient's ability to follow the medication regimen or use of the device (language, education level, functionality)
 - Consult with the authorized prescriber if there are any uncertainties



Nursing Process

The Dispensing Process mirrors and includes the same conceptual steps as the Nursing Process

- Assessment
- Diagnosis
- Planning
- Implementation
- Evaluation





Module 2 Self-Assessment

Please read the scenario below and refer to the next slide to for the related question.

 A 37-year-old mother of five is seen at the LHD. She is seeking a form of birth control, but is frightened of injections or surgery and her partner does not like to use condoms. She has heard oral contraceptives (OCP) are effective and easy to use. The authorized prescriber has written a prescription for OCPs. During your assessment, the client reveals that she smokes "about ½ a pack" of cigarettes per day and has a family history of DVT.



Module 2 Self-Assessment

1. As the LHD RN, what are your next steps as it relates to dispensing?

Select the best answer. Correct answer and rationale are provided on the next slide.

A) Dispense as prescribed and discuss with the client all information concerning OCP use and side effects. Remind patient of her follow-up appointment.

B) Stop the process of dispensing. Consult with the provider about client's smoking and family history of DVT. Verify that the provider wants to continue with this prescription given the new information.

C) Dispense as ordered. Document the current tobacco use in the patient chart for review at the follow-up appointment.



Module 2 Self-Assessment Answers & Rationale

1. The correct answer is B.

The LHD RN must use judgment and consider these factors when dispensing:

- The LHD RN is responsible for ensuring both pharmaceutical and therapeutic appropriateness of the prescription being dispensed. The client is >35 years of age, she is a smoker and she has a family history of DVT.
- These factors combined with the use of oral contraceptives are associated with greater risk. Nursing judgment when dispensing medications or devices should be exercised to ensure patient safety. It is the nurse's responsibility to consult with the provider.



Module 3

Medication and Device Management



Module 3 Content

- The steps involved in establishing medication and device inventory, safety, storage and accountability
- The process for removal and disposal of expired medications from inventory and the management of pharmaceutical recalls
- The LHD responsibilities for receiving medications and devices



Module 3 Objectives

By the end of Module 3 the learner will be able to:

- 1. Identify the requirements for establishing a safe dispensing area
- 2. Identify the elements involved in managing LHD medication inventory
- 3. Follow policies and procedures for ensuring medication safety storage and accountability
- 4. Comply with policies and procedures for the safe handling of expired medications and pharmaceutical recalls



Dispensing Environment

Key elements:

- Area must be clean and organized with adequate work space
- Area should be secure with noise and distractions minimized
- Stock containers and pre-packaged medications must be organized and clearly labeled for safe dispensing
- Environmental conditions (e.g., temperature, light, other) must be maintained to safely store medications and devices
- Support equipment (e.g., pill counters, label makers, etc.) must be available and in working order to aid in dispensing and documentation



Medication Inventory

- Inventory procedures must align with each individual LHD's policies and procedures for receiving and storing medications, but the principles of safe storage, accountability and documentation maintenance remain the same and must adhere to the <u>COMAR 10.34.24.03</u>
- The Responsibilities of the individual receiving medications and devices include:
- Examine medication or device shipments to include shipping containers, cartons and packaging to ensure product integrity is maintained
- Refuse acceptance of potentially damaged or contaminated medications or devices
- Sign the packaging invoice confirming quantity and date of receipt
- Place medications and devices in appropriate and secure designated storage area immediately upon acceptance
- Complete a Medication Inventory Log
- Maintain inventories and records of all transactions regarding receipt and distribution of medications



Recordkeeping: Medication Inventory Log

According to the <u>FDA Code of Federal Regulations Title 21 Sec. 205.50</u> the following are the minimum requirements for the establishment and maintenance of prescription medication distribution records:

- The source of the medications, including the name and principal address of the seller or transferor and the address of the location from which the medications were shipped
- The identity, dates and quantity of each delivery received
- The date and quantity of medication dispensed or disposed of and by whom
- Quantity of the medication remaining in the clinic's stock
- Prescription number as assigned by the LHD
- Date and quantity of medications sent to and received at an alternate site*
 - * Federal 340B Drug Program guidelines for purchase and use apply
- Inventories and records shall be made available for inspection and photocopying by authorized Federal, State or local law enforcement agency officials for a period of 3 years after the date of their creation.


Storage and Accountability

- All medications must be secured in a locked cabinet, storage closet or refrigerator
- Only designated staff should have access to the locked storage areas
- Cabinets or storage areas must be maintained at appropriate temperatures and under appropriate conditions in accordance with manufacturer's recommendations to maintain biologic potency
- Storage areas should have adequate lighting, and be kept clean and organized
- All medication refrigerators must be monitored with appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, and or logs to document proper storage
- Refrigerators used for vaccines and pharmaceuticals may NOT be used for specimens or food storage
- Opioid storage must follow LHD policy and relevant regulations for storage of CIIs: 21CFR 1301.71 and 1301.72 (<u>21CFR 1301.71 Security</u> requirements generally and <u>21 CFR 1301.72 Physical security controls</u>).



Inventory Stock Rotation

- Medications should be stored in a manner that ensures proper rotation of stock
- Stock rotation helps to prevent medication inventory expiration
- Stock rotation also assists in identifying imminent and newly expired medications



Expired Medications

- <u>Expired medications must never be dispensed!</u>
- The process for managing and documenting expired medications is within each LHD Policies and Procedures. Be sure to review your LHD procedure.
- Essential elements with regard to removal from inventory:
 - The medication inventory must reflect whether the medications were returned to the supplier or discarded
 - If medications were discarded, the disposal process must meet the requirements of State and Federal laws



Disposal of Expired Medications

Each LHD should have a Policy & Procedure for inventory removal and disposal of expired medications. Principles to be followed include the following:

- Expired medications must be disposed of appropriately. If unable to be returned to the manufacturer, the only acceptable method for medication disposal is incineration at an approved biomedical waste disposal site
- Flushing or pouring medications down a drain is NOT an acceptable method of disposal
- Documentation of disposal should be maintained on a Medication Inventory Log



Medication Recalls

- LHDs should be alert for voluntary and required medication and device recalls.
- Subscription to "Recalls, Market Withdrawals and Safety Alerts" for U.S. Food & Drug Administration (FDA) can be made at the FDA website <u>here</u>. All that is needed is to subscribe is a valid email address
- The FDA has current information regarding medication and device recalls for both customers and industry
- There should be a designated individual in each LHD to monitor and arrange for immediate removal of a recalled product for return to the manufacturer as stated in the LHD Policy & Procedures



Medication Recall Instructions

The following is the criteria that must be followed based on the Code of Federal Regulations <u>21 C.F.R. § 1317.10</u> and <u>21 C.F.R § 7.59(c)</u>:

- Notation of a recall must be made on the Medication Inventory Log and retained for a minimum of five (5) years
- In the event of a Class I (patient level) Recall, attempts must be made to contact all patients who received the affected medication
- Records documenting contact with patients and returns shall be maintained on-site for at least two (2) years following recall as per <u>COMAR 10.34.24.03</u>
- Maryland Law requires that prescription records be maintained for a minimum of five (5) years as per <u>COMAR 10.34.19.07 A(3)</u>



Module 3 Self-Assessment

- Read each question and select the best answer. Correct answers and rationale are provided on the next slide.
- 1. Upon routine examination of the LHD's medication inventory, the LHD RN notices the stock metronidazole will expire in 3 days. The LHD RN should:
 - A) Wait to dispose of the medication when it is expired

B) Continue dispensing this medication until it expires-it is effective up to six months after the expiration date

C) Document the medication expiration date on the Medication Inventory Log and return it to the supplier for a replacement

D) Inform the nursing manager to assess the inventory

2. The LHD RN is preparing to dispense a 5-day course of metronidazole and discovers that the medication is expiring in 3 days. The RN should:

A) dispose of it in the sink or flush it down the toilet and document the action taken in the Medication Inventory Log

- B) Follow the LHD policy and procedure for medication disposal
- C) Continue to dispense the medication as needed
- D) Rotate expired stock to the back of the storage area or refrigerator



Module 3 Self-Assessment Answers & Rationale

1. The correct answer is C

In most instances medications and devices can be returned to the manufacturer for exchange or credit. Under no circumstances should expired medications be dispensed. The dispensing RN is accountable for every step of the process. This includes ensuring that the medication that is dispensed is not expired and will not be expired within the dosing timeframe. Informing supervisory staff is appropriate but all LHD RNs who dispense should be held accountable for safe practice.

1. The correct answer is B

All other choices are inappropriate actions for the RN to take regarding expired medication inventory. A medication that is expired or will expire during the dosing timeframe should not be dispensed and should either be returned or disposed of appropriately. The only appropriate method of disposal is biomedical waste incineration.



MODULE 4 Strategies for Safe Dispensing



Module 4 Content

- Factors that can affect the dispensing process
- Strategies to reduce errors that may arise within the dispensing process
- Responsibilities of the LHD and the LHD RN, and how each play a role in safe dispensing





Module 4 Objectives

By the end of Module 4 the learner will be able to:

- 1. Describe strategies to promote safe dispensing practices
- 2. Recognize the collaborative roles between the LHD and the LHD RN to provide a safe dispensing environment
- 3. Incorporate strategies within the dispensing process that will reduce dispensing errors



Safe Dispensing Practice

Dispensing errors can occur at many points in a highly complex process involving many decisions, from prescribing and selecting a medication through measuring, labeling, packaging and instructing.





Factors Influencing Safe Dispensing

Factors that *can influence safe dispensing and contribute* to dispensing errors:

- Lack of knowledge or familiarity with the prescribed medication
- Limited access to, and use of, current pharmaceutical references
- Labeling, packaging and selection incongruities (i.e. look-alike packages, sound-alike medications)
- Distracting environment causing interruption and inattention to detail
- Inadequate access to patient information
- An unclear or ambiguous prescription



Responsibilities for Safe Dispensing

Local Health Department <u>Registered Nurse</u>

- Utilize the resources provided
- Maintain and utilize equipment provided
- Keep dispensing area clean and free from distractions
- Maintain and monitor inventory storage areas, including refrigeration units
- Maintain and monitor inventory
- "Successful completion of the Registered Nurses Personally Preparing and Dispensing Drugs & Devices in Local Health Departments" curriculum

Local Health Department

- Provide adequate resources
- Provide necessary equipment
- Provide an appropriate dispensing environment free from distraction
- Provide an area and equipment for safe storage and inventory maintenance
- Provide an opportunity and access to the "Registered Nurses Personally Preparing and Dispensing Drugs & Devices in Local Health Departments" curriculum



Strategies to Promote Safe Dispensing

- Be familiar with available resources, such as the Institute for Safe Medical Practice (<u>http://www.ismp.org/</u>)
- Maintain cleanliness, safety and security of the medication storage area to be sure it is separate from storage of other materials such as cleaning supplies
- Separate pharmaceuticals in designated sections and by distinct product type (i.e., ophthalmic, oral, inhaler, injectable, topical, etc.) within the storage area
- Establish and review the LHD Policy & Procedures for inventory management, including but not limited to: routine stock rotation, expiration inspection, pharmaceutical destruction, and documentation



Strategies to Promote Safe Dispensing

- Maintain open communication and collaboration among clinicians and nurses so that questions and concerns can be easily addressed
- Separate the stock of look-alike and sound-alike medications
- Evaluate labeling (font size, clutter, color) for products purchased, dispensed and repackaged to ensure information can be easily read
- Be familiar with the <u>MDH approved formulary</u> and have a current copy easily accessible
- Be familiar with the medications and dosages most commonly prescribed in your LHD
- Methodically follow each and every step of the Dispensing Process



Other Strategies to Promote Safe Dispensing

Patient Education:

- The LHD dispensing RN has the obligation to inform the patient of the reason the medication and/or device is being prescribed and answer any questions the patient may have
- Inform the patient of the intended/expected effect of the prescribed medication or device, along with any potential adverse reactions and side effects
- Advise the patient of appropriate storage, special instructions, frequency and route of administration and confirm patient understanding
- Explain any other factors that should be discussed as indicated by the patient's history, and psychosocial assessment
- Emphasize the warning to keep the prescribed medication or device out of the reach of children and provide child resistant containers



Medication Dispensing Errors

- Preventing dispensing errors demands a commitment to a zero error standard
- LHDs should strive to create an environment where errors can be used for process improvement
- In an organization where there is often an unwillingness to accept that healthcare workers are human and can/may make mistakes, the result is an environment where errors may be hidden and denied.
- The end result should focus on understanding why the error occurred and how to prevent its occurrence in the future, not finding a focus of blame



Medication Dispensing Errors (continued)

- The LHD RN is responsible for being knowledgeable and complying with the LHD policies regarding dispensing errors.
- If an error occurs in any step of the dispensing process the LHD RN must follow the LHD policy and procedures to:
- Report the error to the nursing supervisor and the prescriber
- Document the occurrence according to the LHD policy for incident reporting



Module 4 Self-Assessment

Read each question and select the best answer. Correct answers and rationale are provided on the next slide.

1. Factors that could impact the occurrence of dispensing errors include:

- A) Limited knowledge about prescribed medication
- **B)** Poor communication
- C) Distractions during the dispensing process
- D) Unclear prescription orders
- E) All of the above

2. The RN recognizes that an error has occurred before dispensing the medication to the patient. What action should the RN take?

- A) Correct the error on the prescription
- B) Report the error to the nursing supervisor
- C) Make a note in the patient's chart describing the potential error

D) Dispense the medication correctly and report the potential error to both the nursing supervisor and the prescribing clinician



Module 4 Self-Assessment Answers & Rationale

- **1.** The correct answer is **E**. All of these factors can contribute to a dispensing error occurrence.
- 2. The correct answer is D.

The RN should report the incident to both the prescribing clinician and the nursing supervisor. Acknowledging potential errors may identify weaknesses in the dispensing practice being utilized and offer an opportunity to identify and implement corrective actions that could prevent future errors. Documenting in the patient's record is only necessary if the medication was dispensed.



MODULE 5

Steps in the Dispensing Process



Module 5 Content

- The Steps in the Dispensing Process
- Rationale for each Step in the Dispensing Process
- Required Elements of a Prescription
- Cautionary warnings



Module 5 Objectives

By the end of Module 5 the learner will be able to:

- 1. List the steps in the dispensing process
- 2. Explain the rationale for each step in the dispensing process
- 3. Recognize the requirements of a properly written prescription
- 4. Identify the legal requirements of documentation
- 5. Distinguish between the different cautionary warnings



The Dispensing Process

A process is a series of actions that lead to a particular result. The process of dispensing occurs in STEPS. These STEPS will be described in the following slides.

The process of dispensing includes:

- <u>Interpreting</u> an authorized prescriber's prescription for a medication or device
- <u>Selecting</u> the medication or device prescribed
- <u>Measuring and packaging</u> the medication or device in accordance with State and Federal law
- *Labeling* the medication or device prescribed
- <u>Documenting</u> the transaction in the patient's medical record



STEP 1 in the Dispensing Process: Interpreting the Prescription

Read the prescription and verify that it includes:

1. Date of issue:

A new prescription may not be filled if presented more than 120 days after issue.

Prescription refills are valid for up to one year from the date of issue. If it is a Schedule III-V controlled substance, authorized refills (maximum of five) are valid up to 6 months from date of issue. Refills are not allowed on Schedule II controlled substances. A maximum of 5 refills in 6 months for Schedule III-V drugs.

- 2. Patient Name (and patient address if the medication is a controlled substance). Date of birth (recommended to prevent errors in cases of common names and family members with the same name)
- 3. Name, address, and telephone number of prescriber (and DEA number if the medication is a controlled substance)
- 4. Name, strength, dose, frequency and quantity of medication
- 5. Route of administration
- 6. Number of refills, if authorized
- 7. Directions for use



Required Elements of a Prescription



***NOTE:** Patient address is required on all controlled substances per 21 C.F.R. §1306.05



STEP 2 in the Dispensing Process: Verification

Verify the following:

- The medication or device is on the approved MDH <u>formulary</u>
- The patient is in need of communicable disease, alcohol and substance misuse, family planning or reproductive health services. This includes Overdose Response Program services and Expedited Partner Therapy
- The prescription is written by an authorized prescriber employed at a LHD
- The only medications and devices that can be dispensed in a LHD are those on the MDH approved formulary and they can only be provided for patients in need of the above named services
- If a LHD would like to add a medication or device to the approved MDH formulary, a <u>written request</u> must be made to the Committee and approval must be granted



STEP 3 in the Dispensing Process: Prescription/Patient Review

Once the prescription order has been verified the Patient information should be reviewed. This includes:

- Allergies
- Concurrent medications the patient is taking, both prescription and over the counter (OTC). This includes vitamins and herbal supplements
- Medical history and comorbidities
- Language proficiency, cognitive ability, literacy, ability to comply



STEP 4 in the Dispensing Process: Selection

Select the prescribed medication or device in accordance with the prescription order:

- 1. Check that it is the correct product in the correct dose and quantity
- 2. Check the product expiration date
- 3. Confirm that it is the correct route and delivery method for the medication or device that has been ordered
- 4. Inspect the medication/device for defects



STEP 5 in the Dispensing Process: Labeling

All dispensed medications and devices must be labeled with the following:

- 1. LHD name, address and phone number
- 2. Patient name
- 3. Phrase "Dispensed by _____, RN" and initials
- 4. Date of dispensing
- 5. Prescriber's name
- 6. Directions for use (frequency and route of administration)
- 7. Name, quantity and strength of the medication
- 8. Manufacturer name (if medication is substituted, include both the prescribed and substitute medication names), lot number and expiration date (see next slide)
- 9. Any special handling instructions regarding proper storage
- 10. Number of refills, if authorized
- 11. Prescription number assigned by the LHD
- 12. Warnings



STEP 5 in the Dispensing Process: Labeling (continued)

For medications or devices dispensed in a container other than the manufacturer's original packaging, an expiration date of the medications or devices shall be the lesser of:

- 1. 1 year from the date of dispensing;
- 2. The month and year when the medications or devices expire;
- 3. The appropriate expiration date for repackaged medications or devices;

For medications or devices dispensed in the manufacturer's original packaging, an expiration date of the medications or devices which shall be:

1. The expiration date set by the manufacturer

From Maryland Statute Health Occupations §12–505.



STEP 6 in the Dispensing Process: Measuring and Packaging

- 1. Measure out the appropriate quantity if unit dosing is not available, using a pill counting tray and spatula.
- 2. Double check accuracy before returning medication to stock
- 3. Select container based on quantity, storage requirements
- 4. Use safety-closure containers only, unless otherwise requested by patient in writing. Note: A prescriber may not give a blanket authorization for the non-use of safety closure containers
- 5. Dispense medications in safety packaging in accordance with <u>Poison</u> <u>Prevention Package Act of 1970</u>
- 6. If manufacturer packaging meets above requirements and has a safety closure it may be dispensed (with appropriate patient label)
- 7. A medication supplied by the manufacturer with patient information leaflets must be dispensed with the leaflet intact.
- 8. Use a new container whenever refilling a prescription
- 9. When dispensing two or more medications to a patient, fill one at a time to ensure no errors occur.



DEPARTMENT OF HEALTH

STEP 7 in the Dispensing Process: Patient Education

- Determine who should receive the medication/device (the patient or the patient's agent).
- Determine patient's level of understanding for both printed and verbal directions. The information should be delivered in a manner that is suitable to the patient's reading ability, language proficiency and in a format the individual will comprehend. Information should include:
 - Correct dosage, route and frequency of administration
 - Proper storage conditions
 - Contraindications/precautions regarding food or other medications that may interact adversely with the medication being dispensed
 - Special considerations
 - Expected benefits
 - Potential side effects
 - Warnings
 - Steps to be taken if a dose is missed



Cautionary Information

Side Effects

• A side effect is any consequence, whether therapeutic or adverse, that is secondary to the one intended in association with the use of a medication or device.

Adverse reactions

• An adverse reaction is an undesirable experience associated with the use of a medication or device and can occur following a single dose or prolonged administration. It may also be the result of a combination of medications. Adverse reactions can range from mild to severe.

Black Box Warnings

• This is the strictest warning placed in the labeling of prescription medications or medication products by the Food & Drug Administration (FDA) when there is reasonable evidence of an association of a serious hazard with a medication.





STEP 8 in the Dispensing Process: Documentation

According to <u>COMAR 10.27.07.07</u> a record of each prescription dispensed <u>must</u> <u>be kept on file for a minimum of 5 years</u> and should include:

- 1. Patient name
- 2. Name of medication/device and manufacturer
- 3. Quantity dispensed
- 4. Date dispensed
- 5. Lot or serial number
- 6. Identification of the dispenser
- 7. Prescription number as assigned by the LHD
- 8. Refills should include date of refill and name of dispenser

Local Health Department should follow the standards for records retention located at:

https://msa.maryland.gov/msa/intromsa/html/record mgmt/homepage.html

Note: Nurses who dispense medications should follow LHD policy on documentation of verbal/faxed/ electronic prescription orders.


Module 5 Self-Assessment

Read the scenario below and select the best answer. Correct answers and rationale are provided on the next slide.

- 1. A LHD RN is working in a busy Family Planning clinic and the clinician has just prescribed a 3-month supply of OrthoCyclen to be dispensed to a patient that was just seen. The LHD RN checks the patient's record, reviews the history, confirms the order, labels and packages the medication according to standard of practice. The nurse collects the educational materials that are most appropriate for the patient's level of understanding. The nurse is about to return to the room and give them to the patient, but gets called to step away for another task. The nurse gives the package with the educational material to the LPN who is also familiar with the patient, provides all of the necessary information to the LPN and asks the LPN to educate the patient on use and side effects, give the materials to the patient and document the transaction in the patient's record. Is this acceptable practice?
 - A) Yes. The LHD RN interpreted, measured, labeled and packaged the prescription. The LHD RN assessed level of understanding and selected the appropriate educational materials.
 - B) No. A LHD RN cannot delegate any step of the dispensing process.



Module 5 Self-Assessment Answer & Rationale

- The correct answer is B).
- No. An LHD RN cannot delegate any step of the dispensing process.



Module 5 Self-Assessment (continued)

Read the scenario below and select the best answer. Correct answers and rationale are provided on the next slide.

2. Read the scenario below and select the best answer.

The TB program is preparing TB meds for their patient who has been ordered for a second line TB medication called pretomanid, a medication that the RN has never given before. Short on time, she quickly pulls the ordered TB medications and makes preparations to do DOT with the patient. Is this acceptable practice?

A) Yes. This is acceptable practice in the MDH Tuberculosis Program.
B) No. The nurse should first check to confirm the medication is listed on the MDH formulary. She should also familiarize herself with side effects of this medication and be prepared to educate the patient about the new medication, how it should be taken and what to do if side effects occur.



Module 5 Self-Assessment Answer & Rationale_(continued)

• The correct answer is B).

B) No. The nurse should first check to confirm the medication is listed on the MDH formulary. She should also familiarize herself with side effects of this medication and be prepared to educate the patient about the new medication, how it should be taken and what to do if side effects occur.



MODULE 6

Treatment of Substance Use Disorder



Module 6 Content

- The distinction between a Certified Opioid Treatment Program (OTP) and other LHD alcohol and substance use disorder or behavioral health clinics
- Medications used for the treatment of substance use disorders that can only be dispensed in a Certified OTP
- Other medications used to treat substance use disorders including naloxone



Module 6 Objectives

- 1. Recognize and apply COMAR regulations for dispensing medications to treat substance use disorders
- 1. Identify the difference between a LHD alcohol and substance use disorder or behavioral health clinics and a Certified OTP
- 1. Relate this distinction to the specific LHD clinic to which this information applies
- 1. Relate information from the previous modules to implement the dispensing process for medications used to treat substance use disorders



Opioid Addiction Treatment/Certified Opioid Treatment Program

- Treatment of opioid dependence with opioid medications is governed by <u>Federal Regulation 42 CFR Part 8</u>, which specifies the procedures required for the establishment of a certified opioid treatment program and the standards that must be followed to dispense opioid medications in the treatment of opioid addiction.
- Unless a LHD has a Certified Opioid Treatment Program (OTP) the LHD RN is not a covered entity to dispense these medications in the LHD. The legal statute that outlines the dispensing standards for nurses working in an OTP can be found in the CFR regulations that provide certification for medication assisted treatment for opioid use disorder.



Opioid Addiction Treatment/Certified OTP (continued)

- Certified OTPs offer a variety of medications to patients with substance use disorder
- These medications support abstinence from opioid use by:
- Blocking the effect of the opioid
- Reducing the withdrawal symptoms a patient experiences
- Reducing the craving for the illicit opioid
- The following medications used to treat opioid use disorder can only be dispensed in a LHD that has met the eligibility criteria, applied for, and received certification as a Certified OTP. These may include: buprenorphine (Subutex), methadone (Dolophine), and buprenorphine/naloxone combination (Suboxone, Zubsolv))



Treatment of Alcohol Use Disorder

In addition to counseling and 12 step programs, medication can assist in the treatment of alcohol use disorder.

Disulfiram (Antabuse) causes unpleasant effects with alcohol consumption within 10 mins after alcohol is consumed.

Common reported untoward effects are:

- Headache/facial flushing
- Nausea/vomiting
- Chest pain/breathing difficulties
- Blurred vision
- Anxiety/confusion

Individuals with substance use and alcohol use disorders often have co-occurring mental health conditions and may be on several medication regimens.



Methadone

- NOTE: Not every LHD has a licensed Methadone Clinic
- However Methadone may be dispensed by a LHD RN in accordance with the <u>MD</u> <u>Health Occupations 8-512</u> (NPA) and regulations adopted by the Board of Nursing (<u>COMAR 10.27.04.01</u>) by a registered nurse (RN) or licensed practical nurse (LPN) working in a methadone clinic licensed by MDH in accordance with:
 - 1. The patient's medication order

2. The methadone clinic's policies and procedures for dispensing methadone and

3. State and federal laws and regulations for dispensing and labeling

• Nurses working in a LHD with a methadone clinic licensed by MDH have both a legal and ethical responsibility to be familiar with these regulations, policies, and procedures.



Naloxone: Legal Authority for Dispensing

On May 25, 2017 Maryland's Governor signed the Heroin and Opioid Prevention Effort (HOPE) and Treatment Act of 2017 into law which allows any "Marylandlicensed pharmacist to dispense naloxone to anyone under the statewide standing order, not only those who have previously been trained and certified under the Maryland Overdose Response Program." This statewide standing order allows pharmacists to dispense naloxone to anyone who may be at risk of opioid overdose or in a position to assist someone experiencing an opioid overdose.

Local Health Department Nurses operating under the Nurse Dispensing Program are not authorized to dispense Naloxone under the HOPE act. In accordance with Maryland law creating the Nurse Dispensing Program, a registered nurse (RN) may dispense naloxone in an LHD if he/she complies with:

- The formulary developed and approved under <u>Health General \$3-403</u>
- The requirements established under <u>Health Occupations §8–512</u> (NPA)



Additional Resources

The following resources are available for further information on Module 6 content:

- <u>Statewide Naloxone Standing Order Guidance for Pharmacy Dispensing</u>
- Information on opioids and opioid treatment programs: <u>Federal Guidelines for Opioid</u> <u>Treatment Programs</u>



Module 6 Self-Assessment

Read the question below and select the best answer. The correct answer and rationale is provided on the next slide.

1. A local resident who has read about the HOPE Act comes to the LHD and is interested in obtaining Naloxone. Can a LHD RN fill this prescription?

A) Yes. She is covered to dispense under the HOPE Act standing order.

B) No. LHD RNs are not covered to dispense under the HOPE Act standing order. This only applies to pharmacists.



Module 6 Self-Assessment Answer & Rationale

- 1. The correct answer is **B**).
- No. LHD RNs are not covered to dispense Naloxone under the HOPE Act standing order. The Hope Act specifies that any Maryland-licensed pharmacist may dispense naloxone to any individual. A LHD RN has the legal authority to dispense Naloxone in a LHD in accordance with:
 - The **formulary** developed and approved under Health General § 3–403
 - The requirements established under <u>Health Occupations § 8–512</u>



Module 6 Self-Assessment

Read the question below and select the best answer. The correct answer and rationale are provided on the next slide.

2. While taking a history from a client in a LHD Family Planning clinic the RN discovers that the client has an adolescent son who she suspects is using misusing illicit substances. The woman asks if she can get Naloxone before she leaves the clinic. What should the RN do?

A) Instruct the woman that she can receive the Naloxone if she completes the Opioid Overdose Response Training and give her information about the next class in her area.

- B) Dispense the Naloxone under the HOPE Act standing order.
- C) Inform the clinician in the clinic so an order can be written for Naloxone.
- D) Refer her to a local pharmacy for the pharmacist to dispense Naloxone under the Hope Act standing order.
- E) A, C, and D



Module 6 Self-Assessment Answers & Rationale

2. The correct answer is E). There are three ways that the LHD RN can assist this individual in accessing Naloxone. The nurse can:

A) Instruct the woman that she can receive the Naloxone if she completes the Opioid Overdose Response Training and give her information about the next class in her area, and

- C) Inform the clinician so that an order can be written for Naloxone.
 - The LHD RN must comply with the requirements of the <u>Health Occupations §8–512</u> (NPA) for dispensing: "to patient's in need of communicable disease, family planning, reproductive health, alcohol and drug abuse services; in compliance with the approved <u>formulary</u>; after successful completion of this training program; maintaining the patient's record in accordance with State and federal laws; in compliance with drug storage and inventory procedures; in accordance with the MDH policy; and *with a prescription from an authorized prescriber employed at a LHD*.

and

D) the LHD RN can refer the individual to their local pharmacy for dispensing by a pharmacist under the HOPE Act standing order.



Module 6 Self-Assessment

Read the question below and select the best answer. The correct answer and rationale are provided on the next slide.

3. A nurse in a LHD can dispense naloxone to the following:

A) An individual who comes to the LHD requesting that the MDH standing order be filled

B) A client seen in the LHD STI clinic who is written a prescription for Narcan by the LHD clinician during their visit

C) A client who comes to the LHD to attend a Naloxone Administration training and requests a Narcan Administration kit after completionD) All of the above



Module 6 Self-Assessment Answers & Rationale

3. The Correct answer is B).

LHD RNs are not covered to dispense Naloxone under the HOPE Act standing order. The Hope Act specifies that any Maryland-licensed pharmacist may dispense naloxone to any individual. A LHD RN has the legal authority to dispense Naloxone in a LHD in accordance with:

- The <u>formulary</u> developed and approved under Health General § 3–403
- The requirements established under <u>Health Occupations § 8–512</u>



MODULE 7

Expedited Partner Therapy



Module 7 Content

- Overview of Expedited Partner Therapy (EPT)
- Goals and benefits of EPT
- Implementation regulations: prescribing and dispensing, documenting and reporting, counseling and education
- Location of resources for clinical guidance and EPT patient, partner, and provider information handouts
- Introduction of new law authorizing EPT treatment for trichomoniasis effective October 1, 2017



Module 7 Objectives

By the end of Module 7 the learner will be able to:

- 1. Describe the principles of Expedited Partner Therapy (EPT)
- 2. Apply the requirements of a prescription/medication label
- 3. Apply the requirements of providing patients with both patient and partner EPT educational materials
- 4. Locate resources for providers and educational materials for patients and partners
- 5. Identify the documentation required for an EPT prescription
- 6. Apply the requirements for morbidity reporting for EPT treatment prescribed or dispensed for a patient's partner(s)



Overview of EPT

An overview of the following will be presented in this module:

- What is EPT?
- Goals and Benefits
- Partners Eligible for EPT
- Prescribing and Dispensing Requirements
- Counseling and Educational Information Requirements
- Documenting Requirements of EPT in a Medical Record
- Healthcare Provider Reporting Requirements

Note: The EPT regulation, <u>COMAR 10.06.07</u>, was revised, effective March 26, 2018 to include Trichomoniasis.



What is Expedited Partner Therapy?

- <u>Expedited Partner Therapy (EPT)</u> is the voluntary clinical practice of providing antibiotic therapy to the sex partners of persons diagnosed with certain sexually transmitted infections (STIs) without a personal physical assessment of the partner, and without having a previous provider-patient relationship with the partner.
- In Maryland, EPT for chlamydia, gonorrhea or trichomoniasis* may be prescribed or dispensed by the following health care providers *in accordance with their current scope of practice:*
 - licensed physicians
 - authorized physician assistants
 - advanced practice registered nurses with prescriptive authority
 - an RN authorized to dispense EPT under the LHD dispensing program
 - licensed pharmacists
- <u>Health General §18–214.1</u> is referenced on the next slide.

*EPT for chlamydia and gonorrhea was authorized in 2015, and trichomoniasis was authorized by amendment in 2017.



EPT: Goals and Benefits

Optimal partner management continues to be direct clinical evaluation, including STI testing, counseling and treatment.

• Note: EPT is not intended to replace direct clinical care and management. It can, however, be a valuable option for reaching partners who are unlikely or unable to seek prompt medical care.

Goals of EPT:

- Reduce the likelihood of re-infection in the index patient
- Contain and stop further spread of the infection
- Prevent complications (e.g. PID, infertility, ectopic pregnancy, epididymitis)

Benefits Include:

- Increase the rate of partner notification
- Increase the rate of partner treatment
- Prevent infection of other partners



Who Should Receive EPT?

Partners Eligible for EPT:

- All sex partners in the 60 days prior to the patient's diagnosis should be considered at risk for infection and should be treated.
- If the last sexual encounter was greater than 60 days prior to diagnosis, the most recent sex partner should be considered eligible
- There is no limit to the number of sex partners

Age of Patient

 Patients of any age with either a clinical and or laboratory confirmed diagnosis of chlamydia, gonorrhea or trichomoniasis infection may be given EPT for their partners

Gender or Sexual Orientation

- Optimal use is in heterosexual patients
- EPT may be used regardless of the patient's gender, but should not be routinely offered to male patients who have sex with other men (MSM) because of the high risk for coexisting infections, especially undiagnosed HIV and/or syphilis, in their partners



Diagnosis and Treatment for EPT

Diagnostic Criteria:

- Patients with either a clinical or laboratory-confirmed diagnosis of chlamydia, gonorrhea or trichomoniasis may be eligible for EPT
- Note: Even if EPT is provided, partners should still be encouraged to seek care as soon as possible to be screened for other STIs/HIV

Treatment:

• Antibiotic therapy prescribed or dispensed for EPT must be in accordance with current treatment recommendations from the Centers for Disease Control and Prevention.



Recommended EPT Medication Regimens: Gonorrhea with/without Chlamydia Co-infection

<u>Gonorrhea (CDC</u>)*:

Gonorrhea only

• Cefixime (Suprax) 800 mg orally in a single dose

Gonorrhea and Chlamydia Coinfection or Chlamydia not ruled out

- Cefixime (Suprax) 800 mg orally in a single dose <u>PLUS</u>
- Doxycycline (Vibramycin) 100 mg orally two times/day for 7 days <u>OR</u> Azithromycin (Zithromax) 1 gram orally in a single dose for partners who may be pregnant or unable to adhere to a 7-day regimen



Recommended EPT Medication Regimens: Gonorrhea (continued)

A Note About Gonorrhea Treatment:

- Current first-line therapy for gonorrhea treatment is intramuscular Ceftriaxone
- The CDC* recommends if a partner of a patient with gonorrhea cannot be linked to evaluation and treatment in a timely fashion, EPT with oral Cefixime should still be considered, as *not* treating partners is significantly more harmful

*CDC. Guidance on the Use of Expedited Partner Therapy in the Treatment of Gonorrhea. <u>https://www.cdc.gov/gonorrhea/hcp/clinical-</u> <u>care/?CDC_AAref_Val=https://www.cdc.gov/std/ept/gc-guidance.htm</u>

*CDC Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/default.htm



Recommended EPT Medication Regimens: Chlamydia

Chlamydia (CDC)*:

- Treat for chlamydia with doxycycline 100 mg orally 2 times/day for 7 days.
 - Substitute Azithromycin (Zithromax) 1 gram orally in a single dose for partners who may be pregnant OR unable to adhere to a 7-day regimen of Doxycycline

*CDC Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/default.htm



Recommended EPT Medication Regimens: Trichomoniasis

Trichomoniasis (CDC)*:

- Presumed vaginal infection:
 ➤ Metronidazole (Flagyl) 500 mg orally 2 times/day for 7 days
- Presumed penile infection:
 ➤ Metronidazole (Flagyl) 2 g orally in a single dose
- Alternative regimen for all non-pregnant partners:
 ➤ Tinidazole (Tindamax) 2 g orally in a single dose

*CDC terminology modified by MDH Center for STI Prevention to anatomic site of presumed infection in order to address limitations of guidance for female/male gender only. Source: MDH CSTIP webpage: https://health.maryland.gov/phpa/OIDPCS/CSTIP/Pages/Expedited%20Partner%20Therapy.aspx



Prescribing and Dispensing Requirements

Prescriptions/Dispensed Medications:

- 1) Must include the designation "Expedited Partner Therapy," or "EPT."
- 2) A separate prescription/labeled pill pack must be issued for each partner.
- 3) If a partner's name is known, the prescription/medication label must be issued in the partner's name in addition to the designation "EPT" or "Expedited Partner Therapy".
- 4) If a partner's name is unknown, the written designation "EPT" or "Expedited Partner Therapy" on the prescription/medication label is sufficient.



Prescribing and Dispensing Requirements, cont'd

- EPT medication labels will include required items noted in all prior modules, as well as:
 - designation "EPT" or "Expedited Partner Therapy"
- The LHD RN must ensure that the EPT prescription:
 - Meets the prescribing requirements before dispensing any treatment
 - Follows all dispensing process steps (Module 5) when dispensing EPT, while allowing for unique use of "EPT" identification when partner name is unknown



Does the partner have allergies? The index patient should be asked and educational information should be provided

Counseling and Educational Information Requirements

Counseling and Educational Information Requirements:

A health care provider prescribing or dispensing EPT to a patient must: 1) Counsel the patient to encourage each partner to seek a personal clinical evaluation; and

- 2) Provide the patient with written educational information* for each partner to include:
 - Information about the STI being treated (chlamydia, gonorrhea and/or trichomoniasis)
 - Medication instructions (as covered in Module 5)
 - Warnings about adverse medication or allergic reactions
 - Advice to abstain from sexual activity until seven days after the last partner has been treated.

*Note: Educational information is available for patients and partners on the MDH EPT website: https://health.maryland.gov/phpa/OIDPCS/CSTIP/Pages/Expedited%20Partner%20Therapy.aspx. It can from another source, as long as it includes the required information above.



EPT: Special Populations

Pregnancy

• Partners receiving EPT who are or may be pregnant should be encouraged to seek a medical evaluation as soon as possible to be screened for other STIs, including HIV, and for referrals to prenatal care, as needed.

Of Note:

• EPT Medications during Pregnancy: Azithromycin, Ceftriaxone, Cefixime, and Metronidazole are considered safe in pregnancy (Category B). Doxycycline is contraindicated during the second and third trimesters of pregnancy, and is not recommended for EPT treatment of partners who are or may be pregnant.



EPT: Special Populations (continued)

- Men Who Have Sex with Men
 - EPT may be used regardless of the patient's gender, but should *not be* offered routinely to male index patient partners who have sex with other men.
 - Due to the high risk for coexisting infections, especially undiagnosed HIV infection, in their partners.
 - Shared clinical decision-making regarding EPT is recommended.

Of Note:

- Concerns about using EPT in MSM include the risk of missing complicated infections, pharyngeal gonorrhea, and undertreating other bacterial STIs.
- Missing concurrent syphilis and/or HIV among MSM is a particular concern in Maryland due to high rates of both infections.


EPT: Special Populations (continued)

- Adolescents
 - Since trichomoniasis is not reportable, the burden of infection in adolescents is not known.
 - Adolescents bear a disproportionate burden of chlamydia and gonorrhea. Although these infections are easily treated with antibiotics, many adolescents are re-infected within 3–6 months, usually because their partners remain untreated.
 - Nonjudgmental, age-appropriate counseling is essential for adolescents when assessing the potential for EPT use for their partners.
 - Assess adolescent patient's comfort level or ability to talk with their partners about EPT. The patient education fact sheets available through MDH Center for STI Prevention include suggestions for how patients might initiate discussions of EPT with their partners.
 - See:

https://health.maryland.gov/phpa/OIDPCS/CSTIP/Pages/Expedited%20Partner% 20Therapy.aspx



Requirements for Documenting EPT

Documenting EPT in a Medical Record:

- A health care provider prescribing or dispensing EPT must document the provision of EPT in the patient's record.
- Documentation must include the:
 - 1) Number of EPT prescriptions or medications provided to the patient for each partner; and
 - 2) Medication and dosage being provided to the patient for each partner.
- Sex partners are not required to have a medical record in order to be provided EPT.

The name of a disclosed partner should not be documented in the patient's record due to confidentiality concerns.



Reporting Requirements for EPT

- Reporting of Chlamydia and Gonorrhea by a Healthcare Provider or Institution:
 - The obligation of a health care provider or institution to report to a health officer cases of Chlamydia and Gonorrhea and the treatment provided to those cases are in accordance with <u>COMAR 10.06.01.04.B</u>. When reporting a case of Chlamydia or Gonorrhea for which EPT was prescribed or dispensed, a health care provider or institution must report the number of partners for whom:
 - 1) Prescriptions were provided; or
 - 2) Medications were dispensed
 - The Maryland Confidential Morbidity Report Form (MDH 1140 form) includes fields to report whether or not EPT was provided for an index patient's partners.
 - Of note: The Morbidity Report Form is a fillable PDF and is available at: <u>https://health.maryland.gov/phpa/Documents/DHMH-</u> <u>1140 MorbidityReport.pdf</u>





- 1. The MDH web page with resources for EPT also includes the EPT statute, regulations, Guide for Health Care Providers, and EPT patient and partner handouts for downloading (meets requirements of patient education resources): https://health.maryland.gov/phpa/oidpcs/cstip/pages/expedited%20partner %20therapy.aspx
- 1. CDC EPT web page at: <u>https://www.cdc.gov/sti/hcp/clinical-guidance/expedited-partner-therapy.html?CDC_AAref_Val=https://www.cdc.gov/std/ept/default.htm</u>



Module 7 Self-Assessment

Please read each question and select the best answer. Correct answers and rationale are provided on subsequent slides.

1. An authorized prescriber gives a LHD RN two prescription orders to dispense to a patient that is being seen in the STI clinic. The 1st prescription order is for the patient, but the second order is to dispense (for the patients' partner) to "EPT," with no name or other patient identifiers. How, if at all, should the medication labels be completed?

A) The LHD RN should dispense the medication for prescription order #1 but should not fill the second prescription order since the demographic data is missing. The RN should ask the provider to complete the information.

B) The LHD RN should dispense the medication for both prescription orders. The label on the first container should be in the index patient's name. The second prescription order should be dispensed and labeled with the index patient's name *and* "EPT" next to the index patient's name.

C) The LHD RN should dispense the medication for both prescription orders and label the first medication container with the index patient's name and the second medication container with "EPT" in the area where the name is usually recorded.



Module 7 Self-Assessment (continued)

1. The correct answer is C).

Both prescription orders should be filled - one for the index patient, one for the partner. (A separate prescription shall be issued for each partner.) The designation "EPT" or "Expedited Partner Therapy" must be included on the face of the prescription for each prescription issued for a partner and the medication should be dispensed and labeled as written. Educational materials should be provided for each prescription dispensed.



Module 7 Self-Assessment (continued)

Please read each question and select the best answer. Correct answers and rationale are provided on subsequent slides.

- 2. The goal of Expedited Partner Therapy is:
 - A) To reduce the likelihood of re-infecting the index patient
 - **B)** To prevent complications of untreated infection
 - **C)** To prevent the likelihood of infecting other partners
 - D) All of the above
- 3. There are no MDH reporting requirements for treatment prescribed and/or dispensed for chlamydia, gonorrhea, or trichomoniasis for a patient's partners

True

False

4. In which of the situations below should the provider consider the patient's sex partners eligible for EPT, assuming other criteria are met?

A) Any partner the patient reports having had sex with in the last 2 months

B) The most recent partner of a patient who has not had sex in the 60 days before diagnosis.

C) A and B



Module 7 Self-Assessment Answers & Rationale

- 2. The correct answer is D). All of the above
- 2. The correct answer is False.

Maryland providers are required to report *the number of EPT prescriptions and/or medications given to the patient for each partner* on the revised Maryland Confidential Morbidity Report Form (DHMH 1140) under section Sexually Transmitted Infection.

4. The correct answer is C).

The most recent partner of a patient who has not had sex in the 60 days before diagnosis. If the patient that has tested positive (or empirically treated) has not had any other sexual encounters in the last 60 days then the last known sex partner should receive treatment. If an individual has been sexually active in the last 60 days prior to diagnosis then all partners within that time frame are eligible for EPT. There is no limit to the number of partners that may be treated.



Module 8

Formulary and other Helpful Links



How to Access Approved Nurse Dispensing Formulary

The Nurse Dispensing approved Formulary and Formulary Request form can be found at:

Pages - Local-Health-Department-Nurse-Dispensing-Committee

Remember:

- Under Maryland law, only medications on the MDH Approved Formulary may be *dispensed* by RNs at the LHD. If there is a medication or device that is frequently requested for dispensing and is not currently on the approved formulary, the LHD must submit a formal request to the Nurse Dispensing Committee for approval. This request can be made through your Health Officer.
- The LHD may have other medications in stock that are not on the formulary that may be *administered*.
 - IM Ceftriaxone is one example.



Other Helpful Links and Resources

- 1. American Nurses Association (2017). About Code of Ethics. Retrieved from <u>http://www.nursingworld.org/codeofethics</u>
- 2. Annotated Code of Maryland Health General §21-220 Food, Drugs and Cosmetics: Prescription requirements. <u>https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=ghg§ion=21-220&enactments=false</u>
- 3. Annotated Code of Maryland Health Occupations §8-511 Nurse Practice Act: Dispensing methadone in licensed clinic. <u>https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=gho§ion=8-511&enactments=false</u>
- 4. Annotated Code of Maryland Health Occupations §8-512 Nurse Practice Act: Registered nurses preparing and dispensing drugs and devices. <u>https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=gho§ion=8-</u> 512&enactments=False&archived=False
- 5. <u>Code of Maryland Regulations (COMAR)</u> 10.47.08 Alcohol and Drug Abuse Administration Overdose <u>Response Program.</u>
- 6. <u>Code of Maryland Regulations (COMAR) 10.06.07 Sexually Transmitted Infections Expedited Partner</u> <u>Therapy for Chlamydia and Gonorrhea.</u>
- 7. Drugs.Com. (Updated Mar 2 2017). Narcan. Retrieved from https://www.drugs.com/pro/narcan.html
- 8. Institute of Medicine. 2003. The Future of the Public's Health in the 21st Century. Washington, DC: The National Academies Press. doi: <u>https://doi.org/10.17226/10548</u>
- 9. Institute of Medicine. 2007. Preventing Medication Errors: Quality Chasm Series. Washington, DC: The National Academies Press. doi: <u>https://doi.org/10.17226/11623</u>



Other Helpful Links and Resources (continued)

- 10. Lachman, V.D., Swanson, E.O., & Windland-Brown, J. (2015). The new 'code of ethics for nurses with interpretive statements' (2015): Practical clinical application, part II. MEDSURG Nursing, 24(5), 363-366, 368. <u>https://pdfs.semanticscholar.org/6635/0a4ab5f074b30645cc984e00b9a8fc857boc.pdf</u>
- 11. National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) (2017). Retrieved from <u>http://www.nccmerp.org/recommendations-statements</u>
- 12. Spivey P. (2012). Ensuring Good Dispensing Practices. In *MDS-3: Managing Access to Medicines and Health Technologies* (Chapter 30). Management Sciences for Health. Retrieved from: <u>https://msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies/</u>
- 13. Substance Abuse and Mental health Services Administration (SAMHSA). Buprenorphine (updated 5/31/2016). Retrieved from <u>https://library.samhsa.gov/product/facts-about-buprenorphine-treatment-opioid-addiction/sma15-4442</u>
- 14. Winland-Brown, J., Lockman, V., Swanson, E. (2015). The new code of ethics for Nurses with Interpretive Statements (2015): Part 1 MEDSURG Nursing 24 (4) 268-271. <u>https://search.proquest.com/openview/6d9d669aa65298264c586243974bb87b/1?pq-origsite=gscholar&cbl=30764</u>
- 15. World health Organization (WHO) (2014) Community Management of Opioid Overdose. Retrieved from <u>http://www.who.int/substance_abuse/publications/management_opioid_overdose/en/</u>



MODULE 9

Post – Test

Go to https://www.surveymonkey.com/r/DHYMMKF

