

PMCY01 Prescription Medication Shortages

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Subject Matter Expert	Pharmacy Unit Director
Approval Authority	HIV/STD Section Director
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1.0 Purpose

To establish uniform procedures used by the HIV/STD Section (Section) for distributing medications when there are prescription drug shortages and communicating information about the shortages to internal and external stakeholders.

The Prescription Medication Shortages Policy and Procedures do not supersede or otherwise circumvent standing delegation orders issued under Texas Administrative Code Title 22, Part 9, Chapter 193.

2.0 Persons Affected

1. Section staff responsible for communicating with local and regional health departments
2. Unit directors and group managers in the Section and Regional and Local Health Operations (RLHO)
3. HIV/STD Section Director
4. Infectious Disease Prevention (IDP) Medical Officer
5. IDP Associate Commissioner
6. Regional medical directors, deputy regional directors, and communicable disease managers

3.0 Responsibilities

3.1 Section Pharmacy Staff:

- Identify or receive notification about drug shortages and assess the situation to determine the magnitude and potential impact of the shortage on program operations.

- Notify affected program managers and staff, the Section Director, and the IDP Medical Officer about the drug shortage and relay existing recommendations and directives regarding the shortage.
- Assess the inventory of the drug in short supply at the time of notification of the medication shortage and continue to monitor the inventory of the drug until the shortage is over.
- Notify group managers, unit directors, the Section Director, and other appropriate leaders when medication supply becomes severely limited.
- Work with pharmacists to adjust order fulfillments based on the drug shortage.
- Ensure agencies ordering the medications through the Pharmacy Inventory and Ordering System (PIOS) are aware of the plan to address the drug shortage.
- Draft communications.

3.2 Section Non-Pharmacy Unit Directors and Staff:

- Provide guidance, expertise, and communication about the drug shortage to internal and external stakeholders.
- Create and disseminate stakeholder communications and supporting documents relating to the drug shortage in consultation with Section Central Office staff.

3.3 Section Central Office Staff:

- Respond in a timely manner to inquiries from providers, contractors, and others who have questions related to the drug shortage.
- Edit stakeholder communications and supporting documents relating to the drug shortage for consistency of messaging, readability, grammar, spelling, punctuation, and formatting prior to routing for approval.
- Communicate with regional and local health departments, communicable disease managers, and the RLHO Public Health Nurse about the drug shortage and how to respond to inquiries.
- Develop tools to help Public Health Region (PHR) staff track the distribution of the affected drugs to providers for the treatment of the affected condition or disease.

3.4 Section Director:

- Provide guidance and expertise as requested.
- Obtain information about the status of the shortage from the Food and Drug Administration and other appropriate federal agencies.
- Work with the DSHS Pharmacy Unit, appropriate Units within the Section, the IDP Medical Officer, and RLHO leadership to ensure they share communication about the drug shortage with contracting agencies, DSHS staff impacted by the shortage, and Texas medical associations, as appropriate.

3.5 The IDP Medical Officer:

- Provide guidance and expertise as requested.
- Review and approve finalized plans to address drug shortages.

4.0 Procedures

4.1 Pharmacy Unit staff identify or receive notification about a drug shortage and assess the situation to determine the magnitude and potential impact of the shortage on program operations. If staff determines the shortage affects the program, the Pharmacy Unit Director notifies the appropriate unit directors or group managers and staff, the Section Director, and the IDP Medical Officer.

4.2 If the drug shortage may severely impact program operations, Pharmacy Unit staff convene a meeting with relevant program staff and managers, the Section Director, the IDP Medical Officer, and one RLHO representative to outline a plan to address the shortage.

4.3 The Pharmacy Unit Director or designee assesses the current inventory of the drugs in short supply at the pharmacy and at the PHRs.

4.4 Section Program staff prioritize populations who receive the identified available supply of the medication in accordance with federal treatment guidelines and recommendations.

4.5 In the event the U.S. Food and Drug Administration or other federal agency has not already identified and announced a drug substitution, the Pharmacy Unit Director consults with the Pharmacy Unit pharmacists and the IDP Medical Officer to identify potential substitute drugs. The Pharmacy Unit Director also identifies funds for purchasing the substitute drug in consultation with the appropriate unit directors. Regional medical directors have the authority to decide which substitute drugs to use in their PHR for both general and priority populations identified in 6.4 while the shortage persists. If an identified substitute drug is available, the Pharmacy Unit offers it through the PIOS portal.

4.6 The appropriate unit directors and the Section Director review the drug shortage plan, including populations identified as priorities for receiving the available supply of the drug in shortage. Once reviewed, the IDP Medical Officer approves the finalized drug shortage plan.

4.7 The appropriate unit directors or group managers work with the designated RLHO representative to inform PHRs about the drug shortage and subsequently maintain communication about the status of inventory until the shortage resolves.

4.8 Program staff disseminate information about the finalized drug shortage plan to internal and external stakeholders.

4.9 The Pharmacy Unit monitors the distribution of drugs in short supply based on the quantity available. If the supply becomes severely limited, the Pharmacy Unit limits the number of drugs sent in orders and notifies the affected stakeholders. The Pharmacy Unit bases the fulfillment of orders for drugs in short supply on the populations prioritized, as determined by Section program staff in consultation with the IDP Medical Officer.

4.10 The pharmacists review orders submitted through the PIOS portal for medication in short supply. The availability and the needs of consumers may limit the quantities supplied for that drug. Pharmacy Unit staff notify the requestor if they make changes to the order in PIOS.

4.11 PHR communicable disease program staff track the distribution of the drug in short supply using the log provided by the Section.

4.12 PHR communicable disease program staff contact designated Section staff or RLHO if a provider or entity cannot obtain the drug in short supply through PIOS. Subsequently, they contact the PHR for assistance in obtaining the medication.

4.13 The appropriate unit directors or group managers inform the IDP Associate Commissioner, RLHO Deputy Associate Commissioner, and RLHO Public Health Nurse of the shortage status on a biweekly basis or more frequently if requested by executive management.

4.14 The Section Director utilizes existing communication channels to inform stakeholders of the shortage status and updates to DSHS' plan for addressing the shortage.

4.15 The Pharmacy Unit Director and the Pharmacy Unit pharmacists continuously monitor the status of the shortage through manufacturers and distributors and communicate manufacturing or distribution status updates to pharmacy stakeholders and affected DSHS programs as needed.

5.0 Revision History

Date	Action	Section
9/16/2024	Changes to Section organizational structure, switch from ITEAMS to PIOS	All
6/7/2019	New Policy	-