Name of Policy:	Drug Shortages	~
Policy Number:	3364-133-89	MEDICAL CENTER
Department:	Pharmacy	
Approving Officer:	Senior Hospital Administrator	
Responsible Agent:	Director of Pharmacy	Effective Date 2/10/2023
Scope:	University of Toledo Medical Center	Initial Effective Date: 2/2/2011
New policy proposal       Minor/technical revision of existing policy         Major revision of existing policy       x         Reaffirmation of existing policy		

# (A) Policy Statement

University of Toledo Medical Centers will take a proactive approach to managing medication shortages. The Department of Pharmacy Services and the Pharmacy and Therapeutics (P&T) Committee are responsible for investigating and providing information about potential drug shortages that may affect patients at the University of Toledo Medical Center and Clinics. The P&T Committee approves any plans for restricting use or rationing limited supplies.

## (B) Purpose of Policy

When the hospital is unable to obtain drug product through the usual commercial channels, patient therapy may be compromised. This policy describes the process for evaluating drug shortages, managing scarce resources, and minimizing impact on patient care.

### (C) Definitions

Drug shortage – a supply issue that affects how the pharmacy department prepares or dispenses a product or influences patient care when prescribers must choose an alternative therapy because of supply problems.

# (D) Procedure

- A. Identifying drug shortages: Staff who identify a real or potential drug shortage should contact the pharmacy department (419-383-4080). The pharmacy department routinely screens for shortages through national databases and the pharmacy group purchasing organizations.
- B. The inventory control specialist will investigate potential drug shortages by contacting all manufacturers of the product to determine current availability.
- C. The inventory control specialist will work through the usual commercial channels such as the drug wholesaler or the manufacturer to purchase supplies of the drug product.
- D. The inventory control specialist will identify available inventory and usual use patterns and will inform pharmacy administration if they are able to purchase additional supplies of the drug.
- E. If the supply situation meets the definition of a drug shortage, the pharmacy department may develop a management strategy in cooperation with the clinicians most affected by the shortage.
- F. The P&T Committee will approve decisions to ration or restrict product to a specific patient populations. The chair of the P&T Committee, in an emergent situation, can approve the use of a non-formulary agent until the shortage is resolved if applicable.
- G. The pharmacy department will notify P&T and affected clinicians about drug shortages via e-mail, newsletters, and/or web site. The information provided will include when applicable:

- a. Products affected
- b. Reason for shortage
- c. Estimated date of product availability
- d. Rationing or restriction strategies
- e. Specific management strategies such as removing product from automated dispensing cabinets and centralizing distribution, or drawing up doses in the IV room to conserve product
- f. Recommendations for alternative agents if appropriate
- H. The pharmacy department will monitor that status of the drug shortage until the supply situation no longer meets the definition of drug shortage. The pharmacy department will provide information about the resolution of a drug shortage via email, newsletter, and/or web site.
- I. Private label products from group purchasing organizations are subject to HRSA's 340B group purchasing organization (GPO) prohibition. If the only product available is private label and failure to supply will compromise patient harm, the private label product will be purchased and records demonstrating the clinical need and lack of availability of alternatives will be documented. The 340B specialist will notify HRSA of the private label product(s) purchased and retain records and documentation related to the purchase for future audits.
- J. The pharmacy will only use approved wholesalers and purchase from DSCSA compliant distributors. Products from "Grey Market" distributors will not be purchased.
- K. Prescribers, nursing, quality management, pharmacy and other stakeholders will be notified of current trends through the Pharmacy and Therapeutics' periodic publication of the "Short List." The Short List indicates current, pending, and resolving medication shortages along with actions taken to mitigate.

#### **References**

- 1. Fox ER, Tyler LS. Managing drug shortages: Seven years' experience at one health system. *Am J Health-Syst Pharm*. 2003;60:245-253.
- 2. American Society of Health-System Pharmacists. ASHP Guidelines on Managing Drug Product Shortages in Hospitals and health Systems. *American Journal of Health-System Pharmacists*. 2009;66:1399-1406.

Approved by: /s/	05/23/2023	<b>Review/Revision Date:</b> 12/13 10/14 11/16
Lindsey Eitniear PharmD, BCPS, AAHIVP Director of Pharmacy	Date	11/19 2/20 2/23
/s/ Russell Smith, PharmD, MBA, BCPS Senior Hospital Administrator <i>Review/Revision Completed By:</i>	05/24/2023 Date	
Pharmacy Policies Superseded by This Policy: None		Next Review Date: 02/01/2026