Name of Policy:	**Manufacturing and Compounding of Drugs**
Policy Number:	3364-133-20
Department:	Pharmacy
Approving Officer:	Senior Hospital Administrator
Responsible Agent:	Director of Pharmacy
Scope:	University of Toledo Medical Center

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 6/01/2023

Initial Effective Date: April 5, 1993

_____ New policy proposal	__X__ Minor/technical revision of existing policy
_____ Major revision of existing policy	_____ Reaffirmation of existing policy

(A) Policy Statement

Records are kept on all items compounded or manufactured by the pharmacy department dispensed to outpatients or other drug administration areas. Records are kept on all inpatient manufactured or compounded items intended for multiple use by a patient.

(B) Purpose of Policy

To provide a uniform record keeping system that includes a record of all products, amounts, manufacturers, lot numbers and expiration dates, used in the preparation of a product dispensed by the pharmacy department. This allows easier duplication of products and provides records in the event of a recall of any individual component.

(C) Procedure

1. All compounding must occur in the pharmacy or by pharmacy personnel. No compounding of medication beyond reconstitution will occur in nursing or procedural areas.
2. All compounds must have a recipe on file. Recipes must be obtained from recognized peer reviewed literature and textbooks. References should be cited on the recipe page. If a compound is needed that currently is not on file, it will be reviewed through the non-formulary process. If approved by the clinical pharmacist based on the literature, a recipe card will be made. This recipe card could be one time or added to the recipe files depending on need.
3. Nonsterile compounding of hazardous medications will follow USP 800 regulations.
4. Compounding information is recorded on the record of manufactured product, by the individual preparing the product.
5. All records of manufactured products have a pre-assigned record number.
6. All records of manufactured products remain in a three-ring binder in the compounding section of the department.
7. All ingredients, quantities, and manufacturer information are recorded in the spaces provided.
8. All additional notes are recorded in the appropriate areas.
9. All products dispensed to other administration areas are appropriately labeled. In addition to special storage requirements and special precautions on administration or usage the labeling shall include a lot number and expiration date. The lot number is the record number and the initials of the individual preparing the product. The expiration date is determined by literature references for the product, the expiration dates of the components, or scientific knowledge, but in no instance shall be longer than one year from the date of manufacture.
10. All medications prepared by someone other than the person administering will be labeled with:

a. Medication name, strength and amount
b. Location to be delivered
c. Directions for use
d. Cautionary/auxiliary stickers
e. Expiration date when not used within 24 hours
f. Expiration date and time within 24 hours
g. Date prepared and diluent for all IV compounds

11. Products dispensed with a prescription to individual patients shall have the record number recorded in the comment area of the prescription.

References: Ohio Administrative Code 4729-17-04
USP 795
USP 800

Approved by:		**Review/Revision Date:**
		5/94
		7/96
/s/	05/23/2023	3/99
Lindsey Eitniear, PharmD, BCPS, AAHIVP	Date	7/02
Director of Pharmacy		7/04
		8/07
		8/10
/s/	05/24/2023	6/13
Russell Smith, PharmD, BCPS, MBA, CPEL	Date	4/16
Senior Hospital Administrator		4/19
Review/Revision Completed By:		6/20
Pharmacy		6/23
		Next Review Date: June 1, 2026
Policies Superseded by This Policy:		