Name of Policy:	**Manufacturing and Compounding of Drugs**	
Policy Number:	3364-133-20	
Department:	Pharmacy	
Approving Officer:	Chief Executive Officer	
Responsible Agent:	Director of Pharmacy	**Effective Date**: 4/1/2019
Scope:	University of Toledo Medical Center	Initial Effective Date: April 5, 1993

_____ New policy proposal	_____ Minor/technical revision of existing policy
_____ Major revision of existing policy	__X__ 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 compounds must have a recipe on file. Recipes must be obtained from recognized peer reviewed literature and text books. 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.
2. Nonsterile compounding of hazardous medications will follow USP 800 regulations.
3. Compounding information is recorded on the record of manufactured product, by the individual preparing the product.
4. All records of manufactured products have a pre-assigned record number.
5. All records of manufactured products remain in a three ring binder in the compounding section of the department.
6. All ingredients, quantities, and manufacturer information are recorded in the spaces provided.
7. All additional notes are recorded in the appropriate areas.
8. 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.
9. 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/	03/28/2019	3/99
Russell Smith, PharmD, MBA, BCPS	Date	7/02
Director of Pharmacy		7/04
		8/07
		8/10
/s/	03/29/2019	6/13
Daniel Barbee, MBA, BSN, RN, FACHE	Date	4/16
Chief Executive Officer		4/19
Review/Revision Completed By:		
Pharmacy		**Next Review Date:** April 1, 2022
Policies Superseded by This Policy:		

The â€œPolicy on Manufacturing and Compounding Drug Products in Canadaâ€ acknowledges compounding as a legitimate part of medical practice, but says it should not be used as a means to bypass the federal drug review and approval system. The policy also states that compounded products must provide a customized medication, without duplicating an approved drug product [23]. 4 Quality Issues with Compounded Medications. 4.1 Quality Testing of Compounded Drugs by Regulatory Agencies. Legal Status. Notice. Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals. A Notice by the Food and Drug Administration on 05/19/2015. Document Details.Â FDA is also announcing the withdrawal of the compliance policy guide (CPG) entitled â€œSection 608.400 Compounding of Drugs for Use in Animals,â€ which was issued in July 2003. This 2003 CPG is being withdrawn because it is no longer consistent with FDA's current thinking on the issues it addresses. DATES