Name of Policy: **Outsourced Compounding**
Policy Number: 3364-133-95
Department: Pharmacy
Approving Officer: Chief Executive Officer
Responsible Agent: Director of Pharmacy
Scope: University of Toledo Medical Center

**Effective Date:** 4/1/2018
Initial effective date 8/1/2012

(A) **Policy Statement:** UTMC Pharmacy will compound IV solutions in compliance with USP 797 standards, in circumstances where the UTMC pharmacy cannot meet the requirements of the standards or literature and resources cannot guarantee product integrity if done internally, outsourcing will be utilized.

(B) **Purpose of Policy:** Provide safe effective compounded parenterals

(C) **Procedure**

I. **503A Compounding Pharmacy:** a traditional compounding pharmacy facility that compounds patient specific prescriptions for home use. 503A compounding pharmacies cannot produce large quantities of product for batch use, and are prohibited from producing office line products.
   a. The UTMC Inpatient Pharmacy acts as an intermediary pick-up location for 503A compounded medications:
   b. A written outpatient prescription must meet Ohio board of Pharmacy requirements for filling will be provided to the compounding pharmacy.
   c. The compounding pharmacy will deliver the medication to UTMC Department of Pharmacy along with an invoice and copy of the original prescription.
   d. The product will be logged in as received.
   e. The invoice and prescription copy will be scanned and attached to the patient’s electronic record
   f. The pharmacist will bill the medication to the specific patient using the non-formulary entry correctly representing the billing amount and verify allergy information
   g. Dispensing records and invoices are stored in the narcotic room
   h. The clinic or unit will pick up the medication in the department of pharmacy, signing that the product was received.
   i. Expired unused products will be wasted through a reverse distributor.

II. **503B Compounding Pharmacy:** a facility that may produce large batches of compounded medication products without prescriptions for the purpose of selling to healthcare facilities for institutional use only. Every process must be validated in a 503B facility in order to comply with FDA, USP and CGMP manufacturing standards.
   a. The procedure for ordering controlled substance products compounded by a 503B facility can be found in 87-IPP, Controlled Substance Ordering System (CSOS) Process. Below details the receiving of compounded products from a 503B facility.
   b. The compounding pharmacy will deliver the medication to UTMC Department of Pharmacy along with an invoice.
c. The product will be logged in as received.
d. Product is sorted based on medication type, location of storage, and DEA schedule.
e. Controlled substance medications are received into the narcotic safe or secured narcotic bins. Remaining products are put away in proper storage locations.
f. Expired unused products will be wasted through a reverse distributor.

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<th>Approved by:</th>
<th>Review/Revision Date:</th>
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</table>
| Russell Smith, Pharm D BCPS
Director of Pharmacy | 3/18 |
| Daniel Barbee RN, BSN, MBA
Chief Executive Officer | Date |

Review/Revision Completed By:
Pharmacy

Next Review Date: 4/1/2021

Policies Superseded by This Policy:

*It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.*