VOLUME 9: PHARMACY SERVICES	Effective Date: 7/08
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9.23.1 REPACKAGING AND COMPOUNDING OF NON-STERILE MEDICATIONS	Attachments: Yes ☐ No ☒

I. PROCEDURE OVERVIEW

Repackaging and compounding of medications shall comply with applicable state and federal regulations. All non-injectable compounded medications shall be considered non-Formulary and shall follow the non-Formulary process. The pharmacy may compound medications which cannot be purchased. The Pharmacist-in-Charge (PIC) is responsible for ensuring compliance with this policy and procedure.

II. PURPOSE

To define methods for repackaging, labeling, and compounding of non-sterile medications.

III. PROCEDURE

A. Repackaging:

1. Medication repackaging shall be done by a pharmacist or by a pharmacy technician under direct supervision of a pharmacist.
2. Repackaging procedures shall conform to practices required by the Food and Drug Administration (FDA) and the United States Pharmacopeia (USP).
3. The Repackaging Batch Control Log Book for each repackaged medication shall include the following information:
   a. Generic medication name
   b. Trade medication name (if any)
   c. Strength
   d. Manufacturer
   e. Manufacturer's lot number
   f. Manufacturer's expiration date
   g. Control number (facility assigned)
   h. Number of units repackaged (total doses repackaged and total packages created),
   i. Date repackaged
   j. Initial of the person repackaging
   k. Initials of the pharmacist completing final check
4. Prior to starting the repackaging process, a pharmacist must check a sample label, verify the product and beyond-use date, and review the Repackaging Batch Control entry in the log book.
   a. Beyond-use date should be one year from the date of repackaging or the manufacturer’s expiration date, whichever is sooner.

B. Labeling Repackaged Medications:

1. Each label of the repackaged medication shall include:
   a. Generic medication name
   b. Trade medication name (if any)
   c. Strength
   d. Manufacturer

e. Manufacturer's lot number
f. Manufacturer's expiration date
g. Control number (assigned)
h. Number of units repackaged
i. Date batch repackaged
j. Beyond-use date
k. Beyond-use date should be one year from the date of repackaging or the manufacturer expiration date, whichever is sooner
l. Initials of the person repackaging

C. Record Keeping:

The Repackaging Batch Log Book must be retained for three years.

D. Compounding Medications:

1. Compounding for a specific patient-inmate shall be done under sanitary conditions by a pharmacist or a pharmacy technician under direct supervision of a pharmacist pursuant to a prescriber's order according to the compounding standards required by the FDA, USP or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding.
2. The Compounding Master Formula Log shall include:
   a. Preparation name
   b. Date of preparation
   c. Original manufacturer's lot numbers for the components (if not known, the source and acquisition date of the components must be recorded)
   d. Original manufacturer's expiration dates for the components (if not known, the source and acquisition date of the components must be recorded)
   e. Pharmacy assigned control number
   f. Expiration date of the finished product (shall not exceed six (6) months from the date of compounding or the shortest expiration date of any component)
   g. Amount of each component used
   h. Manufacturer name(s) of component used
   i. Formula for the compounded product
   j. Method of preparation (in detail can refer to compounding references)
   k. Initials of two persons (at least one (1) of whom shall be a pharmacist) for verification of the steps taken in the compounding process, for checking of calculations of weights of ingredients, and for checking of the final product
   l. Quantity in metric units of finished products or grams of raw materials
   m. Package size and number of units prepared if more than single unit
   n. Sample product label
3. Controlled substances may not be used in compounding.
4. The label shall contain the following:
   a. Preparation name
   b. Date of preparation
   c. List of ingredients
   d. Pharmacy-assigned lot number
   e. Quantity in metric units of finished products or grams of raw materials
   f. Package size
   g. Expiration date

5. The pharmacist shall check the integrity of compounded medication prior to dispensing.
6. The pharmacist shall check the repackaging and compounding logs for completeness on monthly medication quality assurance rounds.

IV. REFERENCES

Food, Drug, and Cosmetic Act Chapter V, Sections 503A. Pharmacy Compounding