



## Pharmacy Services Policy C-020 Repackaging Medications

**A. EFFECTIVE DATE :**

December 23, 2020

**B. PURPOSE :**

To provide a safe and effective process for repackaging medications by pharmacy for hospital use.

**C. POLICY :**

The Pharmacy will be responsible for the repackaging of pharmaceuticals into suitable containers to be supplied as floor stock or for subsequent dispensing to inpatients. Suitable and necessary control procedures shall be utilized to assure conformance to accepted departmental, professional, and regulatory standards.

**D. SCOPE :**

This policy applies to medication distributed from the Department of Pharmacy at John Dempsey Hospital.

**E. DEFINITIONS :**

**Medication Repackaging:** the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.

**Control/Lot Number:** a unique sequence of numbers assigned to a product being repackaged

**Expiration Date:** the date beyond which a product should not be used

**F. MATERIAL(S) NEEDED :**

1. Epic® EMR software/Compounding and Repackaging feature
2. Blister Packs/Oral Syringes

**G. PROCEDURE :**

1. General Instructions
  - a) All repackaging shall be performed in the designated area of the Pharmacy, which should be maintained in a neat, orderly condition. No food or drink in the packaging area.
  - b) Disposable gloves must be worn when packaging medications.
  - c) Repackaging of medication shall occur using the compounding and repackaging feature of the EMR Epic® system. Repackaging of medication may be augmented by utilizing software systems and vendors on an as needed basis. Examples include SafeCor Health® and GoHLabels® systems.
  - d) Personnel who prepackage medications shall be properly trained.

- e) Repackage ONE product at a time and avoid printing labels for several products at the same time. Whenever possible, complete each repackaging operation before beginning another to avoid errors.
  - f) Whenever possible, previously opened manufacturer's bulk containers of drug should be used first.
  - g) A pharmacist or pharmacy technician, under pharmacist supervision, shall determine which products shall be repackaged, what quantity should be packaged to be suitable for internal distribution, and in what sequence.
  - h) Whenever possible, the entire bulk bottle of a product will be repackaged to avoid partial bulk containers.
2. Epic® control (lot) number
- a) An Epic® control (or lot) number is automatically assigned to each batch item being repackaged.
  - b) A separate Epic® control number will be assigned for each different manufacturer or each different manufacturer's lot / expiration used.
- The format for the assigned Epic® control number is the date packaged (YYMMDD) followed by the sequence of the order made that day. The sequence of orders will always be expressed with 3 digits. For example, the Epic® control number for oral solid tablets repackaged as the 10<sup>th</sup> order of the day on August 1, 2020 would be 200801-010. For oral liquids prepackaged as the 3<sup>rd</sup> order of the day on September 1, 2020, it would be assigned a control number of 200901-003.
3. Assigned Expiration/Beyond Use Dates
- a) Expiration dates shall be assigned to all repackaged products. Expiration dates (or beyond-use dates) shall be assigned in accordance with the federal and state laws and regulations. Repackaged medication must never exceed the manufacturer's original expiration date.
  - b) A pharmacist may adjust expiration/beyond-use dates based on current literature using professional judgment.
4. Containers or Packaging Materials
- a) The supervising pharmacist will indicate the packaging containers or materials to be used when standard containers cannot be used, otherwise these standards will be used as below:
    - i) For oral solids: pharmaceutical blister packaging such as those supplied by Health Care Logistics®
    - ii) For oral liquids: Use polypropylene oral syringes (e.g. Exacta-Med Oral Syringe®), glass oral syringes, or oral liquid vials (e.g. amber crimp top/or top fill vials).
5. Product Labels
- a) All products must have a firmly affixed, neat, legible label and must conform to accepted departmental and professional standards. A flat and uncovered barcode is also included or attached to the product to allow for its scanning.
  - b) Label information will include:
    - i) Non-proprietary medication name (i.e. generic medication name)
    - ii) Medication strength (e.g. dosage expressed in metric units)
    - iii) Dosage form (e.g. tablet)
    - iv) Control (or lot) number
    - v) Expiration date or beyond use date
    - vi) Flat barcode
    - vii) Any other information, cautionary statements or warnings necessary (e.g. manufacturer's name and lot number)
6. Repackaging Quality Control Records/Logs
- a) Repackaging quality control records/logs for these medications shall include:
    - i) Date repackaged
    - ii) Medication name, strength, and dosage form

- iii) Manufacturer's name, if known or distributor's name
- iv) Manufacturer's lot number and expiration date
- v) Assigned pharmacy lot number and assigned expiration date
- vi) Number of packages or units prepared
- vii) Name or initials of pre-packager
- viii) Initials of responsible pharmacist(s)

7. Quarantine and Checking Procedures

- a) After completion of prepackaging, the prepared items, manufacturer's containers and the packaging control records are placed in a quarantine area until checked by supervising pharmacist.
- b) The packaging process will be checked by the supervising pharmacist prior to restocking shelves/dispensing to patient.
- i) Particular attention shall be given to:
  - (1) Equipment and supplies (e.g. packaging materials used)
  - (2) Container appropriate for the product and appearance of product
  - (3) Correct medication, strength, and dosage form
  - (4) Correct number of units per package and lot size
  - (5) Seal intact, if applicable
  - (6) Product labeling, incl. legibility and presence of flat, uncovered barcode, as needed
  - (7) Lot (code) number – properly determined and in agreement with containers as well as packaging control records
  - (8) Expiration date assigned
  - (9) Quality control records complete
  - (10) Any other necessary parameters
- ii) Items that do not meet the requirements of this policy shall be corrected or destroyed, as directed by the pharmacist.

**H. ATTACHMENTS :**

None

**I. REFERENCES :**

United States Pharmacopeia (USP).

**J. SEARCH WORDS :**

Medication Repackaging, Packaging, Unit Dose,

**K. ENFORCEMENT:**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**L. STAKEHOLDER APPROVALS :**

On File

**M. COMMITTEE APPROVALS :**

None

**N. FINAL APPROVAL :**

- |   |                           |
|---|---------------------------|
| 1. <u>Andrew Agwunobi, MD (Sign)</u><br>Andrew Agwunobi, MD, MBA<br><b>UConn Health Chief Executive Officer</b>               | <u>01/12/2021</u><br>Date |
| 2. <u>Anne D. Horbatuck (Signed)</u><br>Anne D. Horbatuck, RN, BSN, MBA<br><b>Clinical Policy Committee Co-Chair</b>          | <u>01/11/2021</u><br>Date |
| 3. <u>Scott Allen, MD (Signed)</u><br>Scott Allen, MD<br><b>Clinical Policy Committee Co-Chair</b>                            | <u>01/11/2021</u><br>Date |
| 4. <u>Caryl Ryan (Signed)</u><br>Caryl Ryan, MS, BSN, RN<br><b>VP Quality and Patient Service &amp; Chief Nursing Officer</b> | <u>01/11/2021</u><br>Date |

**O. REVISION HISTORY :**

Date Issued: 9/16/88, 10/16/12

Date Reviewed: 9/2/10, 10/16/12, 7/28/15, 9/10/15, 8/5/16, 12/23/20

Date Revised: 9/2/10, 10/16/12, 7/28/15, 9/10/15, 9/14/20