Pharmacy Department Policy

Bulk Compounding

A. EFFECTIVE DATE:
August 17, 2021

B. PURPOSE:
To provide a standardized process for compounding pharmaceuticals in order to achieve improved delivery of pharmacologic formulations not readily available by a manufacturer.

C. POLICY:
The Pharmacy Department will prepare and distribute pharmaceuticals made during bulk compounding utilizing United States Pharmacopeia (USP) standards for compound preparation. Suitable and necessary procedures shall be utilized to assure conformance to acceptable departmental, professional, and regulatory standards.

D. SCOPE:
This policy applies to Bulk Compounding medication by the Department of Pharmacy for use at John Dempsey Hospital clinical patient care areas.

E. DEFINITIONS:
Control (or lot) number: a unique sequence of numbers assigned to product being packaged.

F. MATERIAL(S) NEEDED:
1. Epic® EMR software/Compounding and Repackaging feature

G. PROCEDURE:
1. Outline of Bulk Compounding Procedures
    a. A compounding worksheet shall be created using the EHR compounding and repackaging feature.
        I. The compounding worksheet includes instructions on how to prepare the compound (i.e. master formulation record or recipe) & a compounding record section to document what ingredients (incl. lot number) were used.
        II. The Pharmacy must obtain literature on any special product either from the prescriber requesting the product or through an acceptable on-line or library references.

b. After receiving an order from a prescriber or for floor stock replacement of the preparation of an item, the pharmacist or technician must locate the manufacturing worksheet within the EHR Compounding and Repackaging system.

c. The manufacturing instructions are reviewed, and any special equipment needed for the procedure is set up. All necessary ingredients, weights, containers, equipment and labels are checked and approved by the supervising pharmacist.

d. Only one preparation is compounded at one time.

e. Gloves shall be worn when compounding bulk preparations.

f. The procedure is performed, following the instructions listed on the compounding worksheet. The necessary information is recorded in the EHR Compounding and Repackaging system.

g. After completion of the procedures, the manufacturing worksheet's compounding record section is filled in and electronically signed by the person compounding the item and pharmacist checking the final product.

h. All products must have a firmly affixed, neat, legible label and must conform to acceptable departmental and professional standards. A flat and uncovered barcode is also included or attached to the product to allow for its scanning.
    I. Label information will include:
        i. Non-proprietary medication name (i.e. generic medication name)
        ii. Medication strength (i.e. dosage expressed in metric units)
        iii. Dosage form
        iv. Control(or lot) number
        v. Expiration date or beyond use date
        vi. Flat barcode
        vii. Any other information, cautionary statements or warnings (i.e. manufacturer's name and lot number)

i. Assigned Expiration/Beyond Use Dates
    I. Expiration dates shall be assigned to all bulk compounded products. Expiration dates (or beyond use dates) shall be assigned in accordance with the federal and state laws and regulations. Bulk compounded products must never exceed the manufacturer's original expiration date.
    II. A pharmacist may adjust expiration/beyond use dates based on current literature using professional judgement

j. Storage
    I. Each bulk compounded product shall be stored in accordance with manufacturer recommendations and federal and state laws and regulations

H. ATTACHMENTS:
None

I. REFERENCES:
United States Pharmacopeia (USP)

J. SEARCH WORDS:
Bulk Compounding, Compounding, Repackaging, Manufacturing

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. Bruce T. Liang, MD (Signed) 11/14/2022
Bruce T. Liang, MD Date
Interim Chief Executive Officer & EVP for Health Affairs
Dean, School of Medicine

2. Anne Horbatuck (Signed) 11/02/2022
Anne D. Horbatuck, RN, BSN, MBA Date
Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 11/04/2022
Scott Allen, MD Date
Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 11/04/2022
Caryl Ryan, MS, BSN, RN Date
Chief Operating Officer, JDH
VP Quality and Patient Services & Chief Nursing Officer

O. REVISION HISTORY:
Date Issued: 1/6/85, 9/22/88, 11/16/92, 12/20/93, 9/19/94, 11/17/97, 6/22/00, 10/17/03, 8/4/09, 8/29/12
Date Revised: 8/29/15, 3/1/17, 08/17/21
Date Reviewed: 8/29/12, 11/9/15, 3/1/17