3.5.23 Repackaging and Compounding Medications

(a) Procedure Overview

Repackaging and compounding of medications shall comply with applicable federal and state regulations. All non-injectable compounded medications shall be considered nonformulary. If compounded medications are needed, California Correctional Health Care Services (CCHCS) shall procure from a licensed compounding pharmacy whenever possible. The Pharmacist-in-Charge is responsible for ensuring compliance with this policy and procedure.

(b) Purpose

To define methods for repackaging, labeling, and compounding medications.

(c) Procedure

(1) Repackaging

(A) Repackaging is governed by the Food, Drug, and Cosmetic Act and the United States Pharmacopeia (USP).

1. Central Pharmacy Services shall register and maintain licensure as a repackager under the Food and Drug Administration (FDA). Central Pharmacy Services shall maintain a complete set of standard operating procedures (SOPs) consistent with current Good Manufacturing Practices (cGMP).
2. Correctional pharmacies within the institution may conduct repackaging services as a pharmacy without registering as a licensed repackager.

(B) Repackaging by Central Pharmacy Services

Beyond-use dating from the Central Pharmacy Services repackager shall be (whichever is shorter):

1. Up to one year from the date packaged as determined by the repackaging materials utilized,
2. The manufacturer's expiration date, or
3. The beyond-use date specified by the manufacturer once the product is opened.

(C) Repackaging by a Correctional Pharmacy

1. Pharmacies shall comply with FDA guidance, which states that pharmacies may repackage drugs under the following conditions:
   a. The facility is licensed by the state as a pharmacy.
   b. The repackaging occurs in the pharmacy:
      1) After receipt of a patient-specific prescription or written chart order, or
      2) Repackaged in advance of a patient-specific prescription based on prior demand for a previous, consecutive 14-day period AND history for 14-day prior periods.
   c. The repackaging is done by or under the supervision of a licensed pharmacist.
   d. The product is repackaged in a way that does not conflict with drug product labeling.
   e. The repackaged drug product conforms to specific beyond-use dating.
   f. The repackaged product is not sold or transferred by a pharmacy other than the one that repackaged the product.
   g. Specific guidance is provided for repackaging drugs on the FDA Drug Shortage List.
2. Prior to starting the repackaging process, a pharmacist must check a sample label, verify the drug product, the beyond-use date, and review the batch control entry in the repackaging log.
3. Pharmacies shall comply with beyond-use dating requirements as set by the USP, which permits repackaged products to bear the shorter of the following dates:
   a. Six months from the date packaged,
   b. The manufacturer's expiration date, or
   c. The beyond-use date specified by the manufacturer once the product is opened.

(D) Repackaging Logs

1. The repackaging logs 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. Initials of the pharmacy staff repackaging
k. Initials of the pharmacist completing final check

2. The pharmacist shall check the repackaging logs for completeness and repackaged medications for expiration and beyond-use dates during monthly medication quality assurance rounds.
3. The repackaging logs must be retained for three years.

(E) Labeling Repackaged Medications

Each label of the repackaged medication shall include:

1. Generic medication name
2. Most common trade medication name (if any)
3. Strength
4. Quantity in the package
5. Manufacturer
6. Control number (facility assigned and unique for each batch of repackaged drug)
7. Date repackaged
8. Beyond-use date as outlined above in Section (c)(1)(C)2
9. Initials of the person repackaging

(2) Compounded Medications

(A) CCHCS pharmacies are not currently equipped and licensed for compounding. If compounded medications are needed, alternative methods of obtaining the product shall be sought.

(B) For sterile compounded medications:

1. Whenever possible, closed systems (e.g., ADD-Vantage, Mini-Bag Plus) and commercially available products shall be dispensed by pharmacy to allow licensed health care staff to prepare at bedside as close to the administration time as possible.
2. If unavailable, the compounded medication may be ordered and prepared by a state-contracted sterile compounding vendor.
3. Refer to HCDOM, Section 3.2.4, Medication Administration, for more details on administering intravenous therapy.

(C) For non-sterile compounded medications:

1. Whenever possible, providers shall prescribe/order and pharmacies shall procure commercially available products that do not require combining ingredients or drugs.
2. If unavailable and with strong clinical justification provided, the compounded medication may be ordered and prepared by a state-contracted compounding vendor.

References

- Business & Professions Code, Chapter 9, Division 2, Article 3, Section 4052.7, Repackaged Previously Dispensed Drugs
- California Code of Regulations, Division 17, Title 16, Article 2, Section 1715, Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
- California Code of Regulations, Division 17, Title 16, Article 4.5, Section 1735, Compounding in Licensed Pharmacies
- California Code of Regulations, Division 17, Title 16, Article 4.5, Section 1735.2, Compounding Limitations and Requirements; Self-Assessment
- California Code of Regulations, Division 17, Title 16, Article 4.5, Section 1735.3, Recordkeeping of Compounded Drug Preparations
- California Code of Regulations, Division 17, Title 16, Article 4.5, Section 1735.4, Labeling of Compunded Drug Preparations
- Health Care Department Operations Manual, Chapter 3, Article 2, Section 3.2.4, Medication Administration
- Food, Drug, and Cosmetic Act Chapter V, Sections 503A. Pharmacy Compounding

- FDA Issues Final Guidance on Repackaging and Revised Draft Guidance on Mixing, Diluting, and Repackaging Biological Products https://www.fda.gov/drugs/drug-safety-and-availability/fda-issues-final-guidance-repackaging-and-revised-draft-guidance-mixing-diluting-and-repackaging#:~:text=Repackaged%20drug%20products%20are%20generally,compounding%2C%20do%20not%20address%20repackaging
- US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities, Guidance for Industry, https://www.fda.gov/media/90978/download
- United States Pharmacopeia: A Guide for the Compounding Practitioner
- United States Pharmacopeia General Chapter <795>, Pharmaceutical Compounding—Nonsterile Preparations

Revision History
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