



<b>VOLUME 9: PHARMACY SERVICES</b>	Effective Date: 12/07
<b>CHAPTER 16</b>	Revision Date (s): 9/13
<b>9.16 EXPIRATION DATES, BEYOND-USE DATES AND DISPOSITION OF OUTDATED, CONTAMINATED, MISLABELED, OR OVERSTOCKED AND RECALLED MEDICATIONS</b>	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

**I. PROCEDURE OVERVIEW**

The Pharmacist-in-Charge (PIC) or designee, and the health care staff shall ensure that no medication is used or administered after its expiration date. Additionally, no contaminated or mislabeled medication shall be used or administered. All outdated, discontinued, mislabeled, or overstocked medications shall be returned to the pharmacy for disposition.

**II. PURPOSE**

To ensure that the medication supply meets state and federal requirements and community standards of practice and to establish a process that separates non-usable medications from the active medication supply.

**III. DEFINITIONS**

**Beyond-Use Dates:** The date beyond which dispensed medication may not be used when different from expiration date.

**Expiration Dates:** Drug manufacturers place expiration dates on the containers/labels of each drug product. Expiration dates are determined by stability assessments that follow scientifically based technical procedures and are approved by the Food and Drug Administration (FDA). Expiration dates apply only when the drug is stored in the manufacturer’s original unopened container under defined conditions.

**IV. PROCEDURE**

**A. Beyond-Use Dates**

1. Medications supplied in the manufacturer’s original packaging and stored appropriately shall be useable until the expiration date (considered to be midnight of the last day of the month indicated, unless otherwise stated) on the package.
2. Repackaged and dispensed medications shall comply with the FDA requirements and United States Pharmacopeia guidelines for determining beyond-use dates.
  - a. For non-sterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers, the beyond-use date shall be one year or less unless stability data or the manufacturer’s labeling indicates otherwise.
  - b. For all other types of non-sterile dosage forms, the beyond-use date is one year or the time remaining of the expiration date.
3. Any drug whose beyond-use date varies from the manufacturer’s expiration date shall be handled as follows:
  - a. Pharmacy shall communicate the beyond-use date to the appropriate staff.

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- b. The staff member that initially opens the container shall date and initial the medication label/container.
- c. All single dose injectables shall be discarded after their first opening, including sterile water for injection.
4. A process shall exist in each health care service area to ensure that medications stored outside the pharmacy are returned to the pharmacy for timely use before they expire.

## **B. Disposition and Use of Master Contracts for the Return or Destruction of Medications**

1. Outdated, contaminated, mislabeled, or overstocked medications will be returned to the pharmacy when identified.
2. Unopened individual patient-inmate medications in sealed containers that have not been issued to the patient-inmate shall be returned to the pharmacy.
3. Any medication that has been delivered to a patient-inmate and returned to pharmacy for any reason shall be considered unusable.
4. The PIC, or designee, shall supervise the disposition of outdated, discontinued, contaminated, mislabeled, or overstocked medications.
5. The pharmacy shall store outdated, contaminated, mislabeled, or otherwise nonusable medications separate from active medication stock until disposition. The non-usable medication storage area shall be clearly labeled.
6. The pharmacy shall utilize vendors contracted through master contracts for the destruction/credit of controlled and non-controlled substances and for the return/credit or destruction of medications that are no longer usable.
7. The pharmacy shall retain records of return, credit, and certificates of destruction documents for a period of three (3) years.

## **C. Medication Recalls**

1. All recalled medications shall be returned to the pharmacy immediately for disposition.
2. The pharmacy will ensure that the recalled medication is unavailable for use and either sent back to the manufacturer or destroyed per the recommendation of the manufacturer.
3. When a medication is recalled by the manufacturer, the PIC shall determine whether the recall has been extended to the pharmacy level or to the patient level.
  - a. Pharmacy Level:
    - 1) If the recall is limited to the pharmacy level, the PIC or designee shall inspect all pharmacy and all patient-inmate care areas. Medications affected by the recall shall be returned to the pharmacy for disposition.
    - 2) The pharmacy will maintain a record of pharmacy level recalls. This record will be kept for a period of three (3) years from the date of the recall.
  - b. Patient Level:
    - 1) If the recall extends to the patient level, the PIC shall identify all patients who may be in possession of the recalled medication(s).
    - 2) The PIC shall notify the Chief Medical Executive, the Chief Nurse Executive, Prescriber and nursing staff in patient-inmate care areas where medication may have been administered or distributed to patient-inmates.
    - 3) Pharmacy shall coordinate replacement of all medications affected by the recall.

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- 4) The pharmacy will maintain a record of patient-level recalls including a list of potentially affected patients and disposition. This record will be kept for a period of three (3) years from the date of the recall.

## V. REFERENCES

- Medical Waste Management Act, California Health and Safety Code, Chapter 6.1, §117635, 117747, 118275, and 118305.
- United States Pharmacopeia