



**LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER**

SUBJECT: USE OF SINGLE-DOSE AND MULTI-DOSE PARENTERAL
MEDICATION VIALS

POLICY NO. 325I

CATEGORY: Provision of Care	EFFECTIVE DATE: 12/14
POLICY CONTACT: Jennie Ung, PharmD	UPDATE/REVISION DATE: 4/22
REVIEWED BY COMMITTEE(S): Pharmacy & Therapeutics	

PURPOSE:

To establish the use and storage requirements for single and multi-dose parenteral medication vials.

POLICY:

Harbor-UCLA Medical Center healthcare providers will practice according to the manufacturer's recommendations in regard to the use of parenteral medication vials. A single-dose vial of parenteral medication will be used for a single case/procedure/injection with a single patient. All multi-dose vials containing parenteral medications will be labeled with a beyond use date at the time of opening.

DEFINITIONS:

Single-Dose Vial: Medications in single-dose vials lack antimicrobial preservatives and are at greater risk to become contaminated and serve as a source of infection when used inappropriately.

Multi-Dose Vial: Medications in multi-dose vials contain antimicrobial preservatives; only vials clearly labeled by the manufacturer for multiple-dose use can be used more than once.

PROCEDURE:

A. Proper Use of Single Dose Vials


1. Used single-dose vials must not be stored for later use, no matter what the size of the vial.

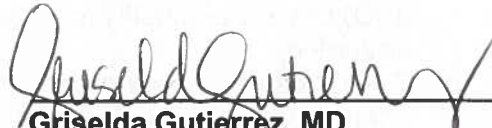
B. Proper Use of Multi-Dose Vials

1. When multiple-dose vials are used more than once, a new needle and new syringe must be used for each entry.
2. In order to minimize contamination of the vial's content, needles or other objects must not be left in vial entry diaphragms between uses.

REVISED: 5/18

REVIEWED: 12/14, 5/18, 4/22

APPROVED BY: 
Anish Mahajan, MD
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Chief Medical Officer


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3. All multi-dose vials containing parenteral medications are to be labeled with a beyond use date at the time of opening.
4. Once punctured, multi-dose vials must be assigned an expiration date of 28 days or the manufacturer's expiration date, whichever is less.
5. Vaccines are exempt from the 28-day limit.
6. Under no circumstances will an assigned expiration date exceed the manufacturer's expiration date.
7. The expiration date shall be written on the label as "MM/DD/YY".
8. A multi-dose vial will be discarded when:
 - a. It is empty;
 - b. Suspected or visible contamination occurs;
 - c. Deterioration is suspected;
 - d. Particulate matter is present;
 - e. The rubber septum is damaged or appears to be leaking;
 - f. It is "cracked" or "leaking";
 - g. It is opened without an expiration date; or
 - h. It is stored outside of the manufacturer's recommendations.

C. Patient Care and Procedure Areas

1. Proper Use of Single-Dose Vials:
 - a. A single-dose/single-use vial must be used for a single patient during the course of a single procedure.
 - b. The vial must be discarded after single use and used vials should never be returned to stock on clinical units, drug carts, anesthesia carts, etc.
2. Proper Use of Multi-Dose Vials:
 - a. Limit the use of multiple-dose vials to only a single patient whenever possible to reduce the risk of contamination.
 - b. The storage of multiple-dose vials must be limited to designated areas outside of immediate patient treatment areas and in accordance with the manufacturer's storage recommendations.
 - c. Disinfect the vial's rubber septum before piercing by wiping it with 70% isopropyl alcohol. Allow the septum to dry before inserting a needle or other device into the vial.

D. Pharmacy Sterile Compounding Areas

1. Proper Use of Single-Dose Vial:
 - a. Single-dose vials opened in less than the International Standardization Organization (ISO) Class 5 air quality must be used within one hour, with any remaining contents discarded.
 - b. Single-dose vials opened in ISO Class 5 air quality can be used for up to six hours.
 - c. Pharmacy staff must disinfect the vial's rubber septum before piercing by wiping with sterile 70% isopropyl alcohol.
 - d. Pharmacy staff must not combine or pool leftover contents of single-dose vials.
 - e. Unopened single-dose vials may only be repackaged in multiple single-dose containers (e.g. syringes) in an ISO Class 5 air conditioner in accordance with standards in the USP Chapter <797> and should be properly labeled with a beyond-use date.



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E. Quality Assurance

1. Pharmacy will conduct monthly quality checks in patient care and procedure areas to look for opened single-dose vials and multi-dose vials without beyond use date.

F. Training

1. All workforce members who administer injections shall receive annual education addressing injection safety and the use of single and multi-dose vials.
2. All patients and caregivers who will use injectable products will be offered discharge education on injection safety through the use of teach-back methods.

G. Reporting

1. Any staff member who becomes aware of injection safety risks, errors, and/or adverse events is to report per Hospital Policy #330 Guidelines for Handling Adverse Drug Events.
2. If unsafe injection and infection control practices are discovered, any affected patients will be notified, assessed for potential harm, and tested for blood-borne pathogens.
3. Infection Prevention Control shall investigate any suspected clusters of infectious disease outbreaks related to the use of these vials and report to local and State Public Health authorities if indicated.

Reviewed and approved by:
Medical Executive Committee on date 04/2022

A handwritten signature in cursive script that reads "Beverley A. Petrie".

Beverley A. Petrie, M.D.
President, Professional Staff Association