



Los Angeles County Department of Health Services

Policy & Procedure Title:		Use of Single and Multi-Dose Parenteral Medication Vials	
Category:	300-399 Operation Policy	Policy No.:	329.017
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DHS Division/Unit of Origin:	Pharmacy Administration		
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Distribution: DHS-wide	<input checked="" type="checkbox"/>	If not DHS-wide, other distribution:	

PURPOSE:

Establish use and storage requirements for single and multi-dose parenteral medication vials within DHS facilities.

DEFINITION(S):

Single-Dose Vial

- Medications in single-dose vials lack antimicrobial preservatives and are therefore 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.

Beyond Use Date

- An assigned date or time, after which the storage or commencing of administration of a drug product or preparation is prohibited.

POLICY:

A single-dose vial or parenteral medication is meant for use in a single patient for a single case/procedure/injection. All multi-dose vials containing parenteral medications are to be labeled with a beyond use date at the time of opening.

The mission of the Los Angeles County Department of Health Services is to ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.

Revision/Review Dates:

Department Head/Designee Approval:

PROCEDURE:

1) Proper Use of Single Dose Vials

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

2) Proper Use of Multi-Dose Vials

- a) When multiple-dose vials are used more than once, a new needle and new syringe must be used for each entry.
- b) In order to minimize contamination of the vial's content, needles or other objects must not be left in vial entry diaphragms between uses.
- c) All multi-dose vials containing parenteral medications are to be labeled with a beyond use date at the time of opening.
- d) Once punctured, multi-dose vials must be assigned a beyond use date of 28 days or the manufacturer's expiration date, whichever is earlier.
- e) Vaccines are exempt from the 28 day limit.
- f) Under no circumstances will an assigned beyond use date exceed the manufacturer's expiration date.
 - i) The beyond use date shall be written on the label as "MM/DD/YY."
 - ii) A multi-dose vial will be discarded when it is opened without a beyond-use date documented on the vial.
- g) A multi-dose or single dose vial will be discarded:
 - i) When it is empty.
 - ii) When suspected or visible contamination occurs
 - iii) When deterioration is suspected
 - iv) When particulate matter is present
 - v) When the rubber septum is damaged or appears to be leaking
 - vi) When it is "cracked" or "leaking."
 - vii) When it is stored outside of manufacturer's recommendations.

3) Patient Care and Procedure Areas

- a) Proper Use of Single Dose Vials
 - i) A single-dose/single-use vial must be used for a single patient during the course of a single procedure.
 - ii) 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.
 - iii) If a single-dose vial must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage, use a new needle and new syringe for each entry and must be used within 1 hour of puncture, or less if specified by the manufacturer. Disinfect the vial's rubber septum before piercing by wiping with 70% isopropyl alcohol. Allow the septum to dry before inserting a needle or other device into the vial.

b) Proper Use of Multi-Dose Vials

- i) Limit the use of multiple-dose vials to only a single patient whenever possible, to reduce the risk of contamination.
- ii) 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.
- iii) Disinfect the vial's rubber septum before piercing by wiping with 70% isopropyl alcohol. Allow the septum to dry before inserting a needle or other device into the vials.

4) Pharmacy Sterile Compounding Areas**a) Proper Use of Single-Dose Vial**

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

5) Quality Assurance

- a) Audit Control Personnel per facility policy will conduct monthly quality checks in patient and procedure areas to look for opened single-dose vials and multi-dose vials without a beyond use date or for those that have expired.

6) Training

- a) All permanent/temporary staff members who administer injections shall receive annual education addressing injection safety and the use of single and multi-dose vials.
- b) All patients and caregivers who will use injectable products will be offered education on injection safety.

7) Reporting

- a) Any staff member who becomes aware of injection safety risks, errors and adverse events are to report to the organization as outlined in facility policy.
- b) 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.
- c) Each local facility shall report clusters of infection or other adverse events to local and state public health authorities.