OLIVE VIEW-UCLA MEDICAL CENTER
POLICY & PROCEDURE

NUMBER: 1587
VERSION: 2

SUBJECT/TITLE: **SINGLE AND MULTI-DOSE PARENTERAL MEDICATION VIALS**

POLICY: The Pharmacy, in collaboration with Nursing and Infection Control shall develop policies and procedures that ensure the safe administration of medications from single and multi-dose vials. A single-dose vial of 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.

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

DEPARTMENTS: All

DEFINITIONS:

- **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

PROCEDURE:

I. General Procedures:

A. Proper use of single-dose vials

i. 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

i. When multiple-dose vials are used more than once, a new needle and new syringe must be used for each entry.

ii. In order to minimize contamination of the vial's content, needles or other objects must not be left in vial entry diaphragms between uses.

iii. All multi-dose vials containing parenteral medications are to be labeled with (1) a beyond use date at the time of opening and (2) the person's initials.

iv. Once punctured, multi-dose vials must be assigned a beyond use date of 28 days or the manufacturer's expiration

date, whichever is earlier. Insulin vials will be assigned a beyond use date of 28 days by pharmacy staff once vials are dispensed.

v. Vaccines are exempt from the 28 day limit.
    1. Multi-dose vaccines that do not require reconstitution can be used through the expiration date printed on the vial [e.g, Inactivated Polio Vaccine (IPOL) 5mL, Influenza Vaccine (Fluzone) 5mL], unless otherwise indicated by the manufacturer.

vi. Under no circumstances will an assigned beyond use date exceed the manufacturer's expiration date.
    1. The beyond use date shall be written on the label as "MM/DD/YY."
    2. Manufacturer's expiration date expressed as "month/year" will be interpreted as the product will expire on the last day of the month.
    3. A multi-dose vial will be discarded when it is opened without a beyond-use date documented on the vial.

C. 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.

II. Patient Care & 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 multi-dose vials to only a single patient whenever possible, to reduce the risk of contamination.
   1. Multi-dose vials of insulin (Regular, NPH, Lispro and Glargine) are exceptions.

ii. The storage of multi-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 vial.

C. Single and multi-dose vials used during ***invasive procedures*** are not subject to this policy. These vials are NOT to be re-used.

III. 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. 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.

IV. Quality Assurance

A. During monthly nursing unit inspection, Pharmacy staff will conduct 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.

V. 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.

VI. Reporting

A. Any staff member who becomes aware of injection safety risks, errors and adverse events are to report to the medication error facility reporting system.
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. Clusters of infection or other adverse events shall be reported to local and state public health authorities.

References: DHS Policies and Procedures – Use of Single and Multi-Dose Parenteral Medication Vials, February 10, 2015.	
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