



Ambulatory Clinic Policy and Procedure

Title: MULTI-DOSE MEDICATION VIALS - USE, HANDLING, AND EXPIRATION	Policy Number: EP 4.9
Regulation Reference: Joint Commission, CDC	Effective Date: 12/2017

Policy Statement:

It is the policy of Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) ambulatory clinics to ensure safe and proper use of multi-dose items within the clinic settings.

Scope and Distribution:

This policy applies to all Texas Tech Physicians of El Paso clinics.

Procedure:

1. A multi-dose vial is a bottle of liquid medication (injectable) that contains more than one dose of medication and is approved by the Food and Drug Administration (FDA) for use on multiple persons. A new, sterile needle and syringe should always be used to access the medication in a multi-dose vial. The reuse of needles or syringes to access multi-dose vial medication can result in contamination of the medicine with microbes that can be spread to others when the medication is used again.

2. Multi-dose vials are to be discarded 28 days after first use, unless the manufacturer specifies otherwise (shorter or longer). Manufacturers are only required by law to test the effectiveness of the bacteriostatic agent used in the multi-dose vial for a period of 28 days. Manufacturers are allowed by the FDA to provide extended dating in the package insert if they have conducted testing beyond the 28 days. Multi-dose pens, such as those used to inject medications such as insulin and Byetta, are included.
 - a. All multi-dose vials must be dated with a 28-day expiration date, defined by The Joint Commission as “the last date that the product is to be used.”
 - b. All multi-dose vials must be initialed at the time of original opening by the person initially accessing the multi-dose vial.
 - c. **Currently, vaccines are EXEMPTED from this requirement.** The Centers for Disease Control and Prevention (CDC) Immunization Program states that vaccines are to be discarded per the manufacturer’s expiration date. The Joint Commission is applying this approach to all vaccines with the understanding that the vaccines are stored and handled appropriately.

3. All personnel will use the aseptic technique when withdrawing medications from multi-dose vials.
 - a. Personnel must clean the access diaphragm of vials using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab.
 - b. Allow the diaphragm to dry before inserting any device into the vial.
 - c. Multi-dose vials of Lidocaine will be treated as single-dose vials.



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4. Discard any vial that has been placed on a contaminated surface or a used procedure tray.
 - a. Keep multi-dose vials away from the immediate patient environment.
 - b. Never store or transport vials in clothing or pockets.
 - c. Never pool or combine leftover contents of vials for later use.
 - d. Never leave a needle, cannula, or spike device (even if it has a 1-way valve) inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.

5. Multi-dose vials should be disposed of in the proper manner if:
 - a. Environmental conditions become detrimental to medication stability.
 - b. The aseptic technique is not adhered to.
 - c. The items become visibly contaminated.
 - d. An opened but unlabeled item is discovered within the clinic setting.
 - e. The medication has expired.

6. Disposal of vials still containing medication will be done through the Safety Services website by submitting a disposal request.

7. Disposed medications should be accounted for via department stock supply.

8. Disposed medications from multiple-use vials shall not be billed unless otherwise allowed by payer policy.

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Signatory approval on file by: Juan Figueroa, M.D. Director of Clinical Operations Clinic Operations Committee, Chair Texas Tech University Health Sciences Center El Paso	