



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: 09/2022

Policy Statement:

It is the policy of Texas Tech Physicians of El Paso (TTP-EP) 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, are included.
 - a. All multi-dose vials must be dated with a 28-day expiration date after first use, to reflect “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 EXEMPT 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.
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.
4. **Multi dose vials of Lidocaine will be treated as single dose vials and discarded after initial use.**
5. **Discard any vial that** has been placed on a contaminated surface.
 - 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
6. Multi-dose vials **should be disposed** of in the proper manner if:
 - a. Environmental conditions become detrimental to medication stability.



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- b. The aseptic technique is not adhered to.
 - c. The items become visibly contaminated.
 - d. An opened, unlabeled item is discovered within the clinic setting.
 - e. The medication has expired.
7. Disposal of vials still containing medication will be placed in the cardboard bin labeled "Pharmaceutical Waste" and a disposal request will be submitted through the Safety Services website
 8. Disposed medications should be accounted for via department stock supply.
 9. 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 Medical Directors Committee, Chair Texas Tech Physicians of El Paso 	