DEPARTMENT: Infection Control **PROCEDURE: IC-325**

SUBJECT: Safe Injection Plan

PURPOSE: To establish a facility wide plan detailing how FMDH will do everything in its power to mitigate risk to our patients from infections that have resulted from the misuse or mishandling of medication vials. By adopting the recommendations outlined by the Safe Injections Coalition, FMDH is making an even deeper commitment to patient safety. This plan is meant to coordinate with the Infection Control Plan (IC-300), the Bloodborne Pathogen Exposure Plan (IC- 320), Pharmacy Service Policy Sterile Products-expiration dates (PS-190), and Nursing Services Policy and Procedure Medication Management (NS-1370).

RESPONSIBILITY: This document is the responsibility of the Infection Control Practitioner (ICP) with input from the Infection Control Committee, the Environment of Care (EOC) committee and the staff members outlined below.

POLICY: FMDH will adhere to the recommendations lined out by the Safe Injections Coalition in regards to the use of injectable mediations (see appendix)
FMDH utilizes the practice of using only one needle, one syringe, one time and single dose vials.
Medications vials will always be entered with a new needle and a new syringe.
Whenever possible, only single-dose/single-use vials of medications will be used.

PROCEDURE:
The following procedures apply to the use of needles, cannulas that replace needles, and intravenous delivery systems.

1) Needles, cannula and syringes are sterile, single-use items. They should never be reused for another patient or to access a medication or solution that might be used for a subsequent patient.

2) Use aseptic technique to avoid contamination of sterile injection equipment.

3) Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.

4) Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use. Once it has been used to enter or connect to a patient's intravenous infusion bag or administration set, consider a syringe or needle/cannula contaminated.

5) Use single-dose vials for parenteral medications whenever possible.

6) The use of multi-dose vials for multiple patients will be reserved for times of extreme drug shortages when all other options have been exhausted and with prior approval of Director of Pharmacy.

7) Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.

8) If multi-dose vials must be used, both the needle or cannula and syringe used to access the multi-dose vial must be sterile.

9) Multi-dose vials for single patient use (i.e. insulin) will be locked in the drawer in the patient's room. Store multi-dose vials in accordance with the manufacturer's recommendations. Discard multi-dose vials if sterility is compromised or questionable. (refer to PS-190 for expiration dates).

10) Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.

11) **Quality Checks:** Regularly occurring quality checks (looking for open vials) as part of the routine stocking/outdate checks of the MedDispense systems performed by the pharmacy technicians. These MedDispense units are housed in all of the clinical areas where medications are stocked (this includes all inpatient areas, the ORs, Glasgow Clinic, and Radiology). Any open vials are to be immediately discarded. Pharmacy will place stickers on all vials for single dosing

12) **Education of staff:** Annual training regarding safe injection practices will be given to all clinical staff via the Health Stream Education program.

13) **Education of patients and family members:** All patients who are discharged from FMDH on an injectable medication (i.e. Lovenox or insulin) receive printed education materials as part of their discharge instructions. These patients/family members also receive one on one teaching about the use of and safety practices while administering these medications.

14) **Internal Reporting of practice/infection control breeches:** All observed breaks in practice that could lead to patient harm from misuse of a vial, needle, or syringe shall be reported to the employee's supervisor and an incident report is to be filled out. It is vital to the safety of our patients that breaks in practices that increase the potential for patient harm be reported to the supervisor, ICP, and the risk manager.

15) **External reporting of adverse events or clusters of infections:** All adverse events are to be reported to the staff member's supervisor, the attending physician, the ICP, administration, and the risk manager. The ICP and risk manager will lead up any investigation into clusters of infections. Any external reporting to (including but not limited to (as applicable): The Joint Commission, in accordance with its Sentinel Event policy, FDA Adverse Event Reporting System (FAERS), county health department, state health department, appropriate patient safety organizations (PSOs), such as ECRI Institute's or the Institute for Safe Medication Practices' (ISMP) National Medication Errors Reporting Program) external agencies will be handled by the ICP, risk manager, administration, and Director of Pharmacy services.

16) **Notification of patient for testing following a BBP or potential exposure:** Patient notification will be the responsibility of the attending physician. Nursing staff will assist the physician with coordinating laboratory testing. Staff members involved or witness to the exposure or break in practice that caused the potential exposure will report this to their supervisor, the ICP, and risk manager via the incident reporting system. The ICP and/or risk manager will alert administration to this exposure or potential exposure and a root-cause analysis will be conducted.

References:

1. CDC's complete 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, which includes recommendations on safe injection practices, see the CDC website at: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf
2. APIC position paper: Safe injection, infusion, and medication vial practices in health care
Susan A. Dolan, RN, MS, CIC, Gwenda Felizardo, RN, BSN, CIC, Sue Barnes, RN, BSN, CIC, Tracy R. Cox, RN, CIC, Marcia Patrick, RN, MSN, CIC, Katherine S. Ward, RN, BSN, MPH, CIC, and Kathleen Meehan Arias, MS, CIC Washington, DC
3. The Joint Commissions Sentinel Event Alert Issue 52, Preventing Infections from the misuse of vials. June 15, 2014.

REVIEW PROCESS: There will be an annual evaluation of this Safe Injections Plan in terms of its objectives, scope, and performance, and effectiveness. This review will happen annually or sooner if necessary. Reviewers of this document include but are not limited to: Infection Control Practitioner, Director of Pharmacy Services, Director of Nursing Services, Environment of Care Committee, Physician Advisor, FNP, CEO, and the Board of Trustees. (Original document date 08/2014).

Appendix A

Recommendations: these are supported by the CDC guidelines III.A.1b. Recommendations IV.H.1-8.

Single-dose/single-use vials

- Use a single-dose/single-use vial for a single patient during the course of a single procedure. Discard the vial after this single use; used vials should *never* be returned to stock on clinical units, drug carts, anesthesia carts, etc. The One & Only Campaign from the CDC and Safe Injection Practices Coalition emphasizes ONE needle, ONE syringe, ONLY ONE time. Medications in single-dose/single-use vials lack antimicrobial preservatives and are therefore at greater risk to become contaminated and serve as a source of infection when used inappropriately. See campaign resources, including video.
- If a single-dose/single-use 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. Note: USP 797 states that single-dose/single-use vials opened in less than ISO Class 5 air quality be used within one hour, with any remaining contents discarded. Single-dose/single-use vials opened in ISO Class 5 air quality can be used up to six hours.
- Do not combine or pool leftover contents of single-dose/single-use vials. Do not store used single-dose/single-use vials for later use, no matter what the size of the vial.
- Unopened single-dose/single-use vials may be repackaged into multiple single-dose/single-use containers (e.g. syringes), which should be properly labeled, including the expiration date and a beyond-use date (which is different from the manufacturer assigned expiration date). This repackaging should be performed only by qualified personnel in ISO Class 5 air conditions in accordance with standards in the United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding - Sterile Preparations. Also, follow the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container.

Multiple-dose vials

- Only vials clearly labeled by the manufacturer for multiple dose use can be used more than once.
- Limit the use of a multiple-dose vial to only a single patient, whenever possible, to reduce the risk of contamination.
- When multiple-dose vials are used more than once, use a new needle and new syringe for each entry. Do not leave needles or other objects in vial entry diaphragms between uses, as this may contaminate the vial's contents.
- Disinfect the vial's rubber septum before piercing by wiping (and using friction) with a sterile 70 percent isopropyl alcohol, ethyl/ethanol alcohol, iodophor, or another approved antiseptic swab. Allow the septum to dry before inserting a needle or another device into the vial.
- Once a multiple-dose vial is punctured, it should be assigned a "beyond-use" date. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.
- Store multiple-dose vials outside the immediate patient treatment area; observe the manufacturer's storage recommendations.

All vials (single-dose/single-use and multiple-dose)

- Discard any vial if its sterility has been compromised or is questionable, including those having been placed on a used procedure tray or used during an emergency procedure – even if the vial is unopened/unused.
- Select the smallest vial necessary when making purchasing and treatment decisions to reduce waste.
- Urge manufacturers to produce vials in appropriate sizes to reduce waste.