Department of Veterans Affairs **VHA DIRECTIVE 2008-027**
Veterans Health Administration
Washington, DC 20420 **May 13, 2008**

THE AVAILABILITY OF POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy regarding the use of Potassium Chloride for Injection Concentrate USP.

2. BACKGROUND

a. In recent years, numerous reports have been published in the medical literature of adverse events and deaths caused by errors in the use of Potassium Chloride for Injection Concentrate USP. This matter has been discussed on numerous VHA Central Office pharmacy conference calls. Many facilities have already removed Potassium Chloride for Injection Concentrate USP and other hypertonic injectables from patient care areas.

b. VHA policy requires that a pharmacy-managed Intravenous (IV) admixture program be responsible for the labeling, preparation, and distribution of IV admixtures. Understanding that some IV admixtures may not be prepared by the Pharmacy Service, practices and policies must be in place to ensure the IV admixtures not prepared by the Pharmacy Service are compatible with the policies that govern the pharmacy-prepared IV admixtures. Only pre-diluted or pre-mixed Potassium Chloride for Injection Concentrate USP can be administered under the immediate-use provision as described in the USP Chapter 797, "Pharmaceutical Compounding - Sterile Preparations."

c. To meet patient needs, the use of manufactured “pre-mixed” large volume solutions, including those with potassium chloride, may be used in conjunction with a pharmacy-managed IV admixture program.

3. POLICY: It is VHA policy that Potassium Chloride for Injection Concentrate USP must not be stored in any patient area, nor provided to the health care provider to be administered to the patient at bedside.

4. ACTION

a. **Facility Director.** The facility Director is responsible for:

(1) Ensuring Potassium Chloride for Injection Concentrate USP is only utilized as part of a pharmacy-managed IV admixture program; therefore, storage of the medication must be in the pharmacy and is the responsibility of the Pharmacy Service.

(2) Ensuring all Potassium Chloride for Injection Concentrate USP is removed from all wards, intensive care units, operating suites, and clinics. ***NOTE:*** *It is not to be considered as ward stock.*

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(3) Ensuring written medication use policies are established that include guidance regarding safe handling of Potassium Chloride for Injection Concentrate USP, which must specifically state that:

(a) It is VA policy not to have Potassium Chloride for Injection Concentrate USP and other hypertonic injectable solutions on the wards and similar sites,

(b) Normal or routine VA practice is for IV solutions to be mixed centrally,

(c) Cardioplegic solutions are prepared by, or supplied by, Pharmacy Service only,

(d) Unit dose drug distribution is required for inpatient areas.

b. **Chief Pharmacy Service.** The Chief, Pharmacy Service, or designee, at VA medical facilities that perform heart transplant and open heart surgery, is responsible for ensuring:

(1) Cardioplegic solutions are only prepared by, or supplied by, the Pharmacy Service.

(2) Those solutions are hand-delivered to the operating room (OR) by Pharmacy Service.

(3) Those solutions are clearly labeled "For Cardioplegia Only," and contain the patient's name.

(4) Those solutions are secured in one location in, or adjacent to, the cardiac surgery suite, i.e., the OR automatic medication dispensing machine or the locked perfusionist's cabinet.

(5) Access is limited to the cardiac surgeon, cardiac anesthetist, cardiopulmonary bypass technician (perfusionist), and the OR pharmacist.

c. **Chief, Anesthesia Service.** The Chief, Anesthesia Service, is responsible for:

(1) Identifying the secure location for Potassium Chloride for Injection Concentrate USP in the cardiac surgery suite;

(2) Ensuring that the correct solution is verified for use in the correct patient;

(3) Providing for the disposition of any unused cardioplegic solutions; and

(4) Developing, publishing, and maintaining a local policy that ensures the accountability and safety of the drug.

5. REFERENCE: Pharmaceutical Compounding – Sterile Preparations (general information chapter 797). In. The United States Pharmacopeia, Second Supplement to USP 31 – NF 26. Rockville, MD; United States Pharmacopeial Convention: 2008: 1-61.

6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant for Pharmacy Benefits Management (PBM) Services (119), in the office of Patient Care Services, is responsible for the contents of this Directive. Questions may be directed to 202-461-7326.

7. RESCISSIONS: VHA Directive 99-031 is rescinded. This VHA Directive expires May 31, 2013.

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