SAFE MEDICATION INJECTION PRACTICES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive states the policy and assigns responsibility for the safe management of medication syringes, needles, medication vials, infusion pumps used for the delivery of medication therapy and diagnostic injection practices.

2. SUMMARY OF MAJOR CHANGES: Amendment, dated June 24, 2024 removes the language found in paragraph 4.b that requires creation of local VA medical facility policies on safe medication injection practice. This amendment is required by VHA Notice 2024-08, Suspension of Local Policy Mandates in Overdue VHA National Polices, dated June 24, 2024, which suspends implementation of this local policy mandate.

3. RELATED ISSUES: The policy will be effective within 120 days after the publication date of the Directive.

4. RESPONSIBLE OFFICE: The Office of Nursing Services (10A1) is responsible for the contents of this Directive. Questions may be directed to 202-461-6700.

5. RESCISSIONS: VHA Directive 2008-027, The Availability of Potassium Chloride for Injection Concentrate USP, dated May 13, 2008, is rescinded**.**

6. RECERTIFICATION: This VHA Directive is scheduled for recertification on or before the last working day of July 2020.

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SAFE MEDICATION INJECTION PRACTICES

1. PURPOSE: This Veterans Health Administration (VHA) Directive states the policy and assigns responsibility for the safe management of medication syringes, needles, medication vials, infusion pumps used for the delivery of medication therapy and diagnostic injection practices. **AUTHORITY:** 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND:

a. **Syringe and Needle Utilization.**

(1) VA has set standards for the appropriate labeling of medication containers including syringes. Patient Safety Alert AL12-03, see subparagraph 5d, requires that all medications on and off the sterile field, not intended for immediate use, must be labeled with the medication name, strength, quantity, diluent and volume (if not apparent from the container), and the expiration date or time. Sterile preprinted medication labels should be available and utilized to identify the container in which the medication is held. All unlabeled solutions or medications are to be immediately discarded.

(2) The U.S. Department of Labor Department of Occupational Safety and Health Administration (OSHA) prohibit recapping of needles, with few exceptions, see subparagraph 5e. VHA Directive 7701, Occupational Safety and Health (OSH), establishes the policy and assigns responsibility for the OSH program in accordance VA Directive 7700, see subparagraph 5f.

b. **Medication Vial Utilization.**

(1) The VA Medical Advisory Panel (MAP) on March 19, 2009, adopted VA guidance to use one medication vial per patient. In other than immediate use situations (as defined by United States Pharmacopeia (USP) Chapter 797: Pharmaceutical Compounding—Sterile Preparations, a vial of medication should not be used on more than one patient regardless of whether it is a multi-dose vial (MDV) or an single dose vial (SDV).

(2) The CDC, in their Injection Safety checklist, indicates one safe injection practice as: “Multi-dose vials are dedicated to individual patients whenever possible.” See subparagraph 5h.

c. **Smart Infusion Pump Utilization.**

(1) The Joint Commission standard MM.02.01.01 requires establishing standardized drug concentrations, see subparagraph 5i, and The Institute of Safe Medication Practices (ISMP) in 2008, see subparagraph 5j, and 2012, see subparagraph 5k, recommends using those standardized concentrations in setting smart pumps guardrail limits.

3. POLICY: It is VHA policy to ensure the safe use of injectable medications.

4. RESPONSIBILITIES:

a. **Veterans Integrated Service Network (VISN) Director.** The Veterans Integrated Service Network (VISN) Director is responsible for ensuring that facility directors comply with the policy requirements in this Directive.

b. **Facility Director.** The facility director is responsible for ensuring that:

(1) The staff competencies related to safe medication practice procedures are assessed on an annual basis;

(2) Medication vials are available that meet the needs of medical providers and minimize waste; and,

(3) Alternate practices to maximize medication availability are implemented during times of critical medication shortages to maintain the highest level of patient safety.

c. **Clinical Executives (Chiefs of Staff (COS), Pharmacy (COP) and Associate Director for Patient Care Services / Chief Nursing Officers) (ADPCS/CNO).** The clinical executives are responsible for ensuring that the policy will address at a minimum, the following:

(1) **Concentrated Potassium Chloride (KCL).** Concentrated KCL is prohibited from being stored in patient care units.

(2) **Labeling of Medications.** In perioperative and other procedural settings both on and off the sterile field, medications must be labeled with information consistent with the requirements of Patient Safety Alert AL12-03, see subparagraph 5d.

(3) **Insulin Vials.** Multi-dose vials of insulin should be dedicated to a single person whenever possible. If the vial must be used for more than one person, it should be stored and prepared in a dedicated medication preparation area outside of the patient care environment and away from potentially contaminated equipment. Insulin vials will always be entered with a new sterile needle and syringe.

(4) **Multi-dose Pen Injectors.** Multi-dose pen injectors are prohibited for use within VA inpatient care units (i.e., any unit where a staff member is involved in the storage, preparation or administration of a multi-dose pen injector). The following exceptions apply:

(a) Patients being educated, prior to discharge, on the use of a patient-specific multi-dose pen injector;

(b) Eligible patients participating in the VA medical center's Self-Medication Program (SMP) as established by VHA Handbook 1108.03, Self-Medication Programs (SMP);

(c) Patients requiring treatment with a medication delivered in a pen injector and no alternative formulation is available from the manufacturer for treating the patient while on a patient care unit; or

(d) Patients participating in a research protocol requiring a multi-dose pen injector while on a patient care unit.

(5) **Syringes and Needles.** The reuse of syringes and needles on multiple patients is prohibited. Needles and syringes should be disposed of immediately after use in a facility- approved sharps waste disposal container. All medication syringes not intended for immediate use must be labeled with the medication name, strength, quantity, diluents and volume (if not apparent from the container), and expiration date and time, if appropriate.

(6) **Medication vial**. In other than immediate use situations, a vial of medication should not be used on more than one patient, regardless of whether it is a multi-dose vial (MDV) or a single dose vial (SDV). Insulin and vaccine vials are exceptions. Also, any injectable medication prepared using aseptic processing are exceptions to this policy.

(7) Adopt standard concentrations of medications identified as high alert medications by the VA medical facility. This requirement does not restrict the ability to set expanded dosing limits for anesthesia providers practicing in an operating or procedural setting.

(8) The defined VA medical facility standard concentrations of high alert medications are programmed into the facilities smart infusion pumps.

(9) Eliminate the capability for non-anesthesia provider staff to program non-standardized medication concentrations into the smart pump, except that, at the discretion of the VA medical facility, non-anesthesia providers and staff may retain the capability to program non-standardized concentrations into smart infusion pumps if they have received specific training regarding programing and receive an annual competency assessment.

(10) Activate smart infusion pump safety guardrails including minimum concentrations.

5. REFERENCES:

a. Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC). One and only campaign. Safe injection practices: education materials for safe use. December 2012. Accessed on July 16, 2013. http://www.oneandonlycampaign.org/safe_injection_practices

b. Patient Safety Alert, VHA Alert AL 13-04, January 17, 2013 http://www.patientsafety.va.gov/alerts/AL13-04MultiDosePens.pdf

c. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2389

d. Patient Safety Alert, VHA Alert AL 12-03, February 9, 2012 http://www.patientsaftey.va.gov/alerts/AL12-03EpinephrineWWW.pdf

e. 29 CFR 1910.1030.

f. VHA Directive 7701. Occupational Safety and Health (OSH). August 9, 2010. http://www.va.gov/vhpublicatoins/View/Publication.asp?pub ID=240

g. Patient Safety Advisory, VHA Advisory 09-03, October 21, 2008 http://vaww.ncps.med.va.gov/Guidelines/alerts/Docs/MultidoseVialsAD09-03.pdf

h. CDC Injection Safety Checklist. Accessed on July 16, 2013. http://www.cdc.gov/injectionsafety/PDF/SIPC_Checklist.pdf

i. Joint Commission standard MM.02.01.01, Accessed March 2013.

j. Institute for Safe Medication Practices (ISMP) Medication Safety Alert August 28, 2008 http://www.ismp.org/newsletters/acutecare/archives/Aug08.asp#28

k. ISMP Medication Safety Alert February 23, 2012 http://www.ismp.org/newsletters/acutecare/issue.asp?dt=20120223

l. The United States Pharmacopeia (USP) Convention (USPC). Chapter 797: Pharmaceutical Compounding—Sterile Preparations. In: The United States Pharmacopoeia, 30th ed., and the National Formulary, 25th ed. Rockville, MD: USPC; 2012.

6. DEFINITIONS:

a. **Aseptic Processing.** Aseptic processing means a mode of processing and transferring pharmaceutical and medical products in at least an International Standards Organization (ISO) Class 5 environment. See subparagraph 5l.

b. **Immediate Use.** Immediate use refers to when an authorized staff member prepares a parenteral product not intended for storage and for immediate patient administration without any break in the process. If administered by a staff member other than the person who prepared it, the product shall be appropriately labeled based on local VA medical facility procedures and be administered within one hour of preparation.

c. **Multi-dose Pen Injectors (e.g. Insulin Pens).** Multidose pen injectors are pen-shaped injector devices designed for drug delivery that are intended for use by a single person.

d. **Multi-Dose Vial (MDV).** United States Pharmacopeia (USP), Chapter 797 defines MDVs as multiple-unit containers (such as vials) for articles or preparations intended for parenteral administration only. MDVs usually contain antimicrobial preservatives, which permit removal of portions on multiple occasions. The beyond-use-date (BUD) for an opened or entered (e.g. needle punctured) multiple-dose vial with antimicrobial preservatives from date of mutual entry is 28 days unless otherwise specified by the manufacturer.

e. **Needle.** A needle is a slender hollow instrument for parenteral introduction of material into the body or for removing material from the body.

f. **Single Dose Vial (SDV).** USP, Chapter 797 defines a SDV as a single-unit container for articles or preparations intended for parenteral administration, only and, intended for a single use, such as prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers, when so labeled.

g. **Smart Infusion Pump.** A smart infusion pump is a programmable infusion pump with dose-checking technology designed to avert potentially harmful administration errors.

h. **Syringes.** Syringes are instruments intended for the injection of medication, water or other liquids into the body or its cavities.

i. **Guardrails.** For the purposes of this Directive, guardrails are maximum and minimum parameters embedded into the software of a medication delivery pump with the purpose of identifying inadvertent programming errors or medication dosages outside predetermined ranges.