HIGH-ALERT MEDICATIONS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes VHA policy and standards for an enterprise-wide high-alert medication list created and maintained in collaboration with the Defense Health Agency (DHA). Consistent with ongoing efforts to improve patient safety, medications identified on the national high-alert medication list may be subject to certain required risk mitigation strategies established within the combined electronic health record (EHR). In addition, this directive outlines the VHA policy and standards for the administration, ambulatory care settings and clinic storage, labeling, inventory, and return of high-alert medications at Department of Veterans Affairs (VA) medical facilities.

2. SUMMARY OF CONTENT: This VHA directive:

a. Identifies Pharmacy Benefits Management (PBM) Service and Office of Nursing Services (ONS), in collaboration with DHA as business owners for high-alert medication management standards.

b. Defines the process for designating high-alert medications and how the VHA/DHA High-Alert Medication List will be maintained (see Appendix A).

c. Provides direction regarding administration, methods to reduce potential errors, storage, inventory, and return of high-alert medications (see Appendix D).

d. Provides VHA and DHA a universal high-alert medication list that is standardized for current and future implementation of a combined electronic health record (EHR) (see Appendix G).

3. RELATED ISSUES: VA Handbook 0730/4, Security and Law Enforcement, dated March 29, 2013; VHA Directive 1108.07(1), General Pharmacy Service Requirements, dated November 28, 2022; VHA Directive 2013-006, The Use of Unlicensed Assistive Personnel (UAP) in Administering Medication, dated March 5, 2013.

4. RESPONSIBLE OFFICE: The Executive Director, Pharmacy Benefits Management Service (12PBM) and the Executive Director, Office of Nursing Services (12NUR) are responsible for the content of this directive. Questions may be referred to VHA12PCSAction@va.gov.

5. RESCISSIONS: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive becomes effective 24 months after publication. Within 24 months of publication of this directive, VA medical facilities must meet the requirements in this directive. PBM will request progress updates on a quarterly basis from VA medical facilities to monitor the implementation plan to comply with policy requirements.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ M. Christopher Saslo
DNS, ARNP-BC, FAANP
Assistant Under Secretary for Health
for Patient Care Services/CNO

DISTRIBUTION: Emailed to the VHA Publications Distribution List on December 9, 2024.

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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1. PURPOSE

The purpose of this directive is to establish a jointly agreed upon universal high-alert medication list applicable to the Veterans Health Administration (VHA) and Defense Health Agency (DHA). This VHA directive establishes the minimum standards and requirements that must be followed by all VHA health care providers in both inpatient and outpatient clinical settings for administration, storage, labeling, inventory and return of high-alert medications. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. BACKGROUND

a. High-alert medications are medications, medication classes or medication categories that are associated with the highest risk of morbidity and mortality when inappropriately dosed, administered or monitored. Although mistakes may or may not be more common with these drugs, the consequences of an error are typically more devastating to patients. Historically, VA medical facilities have utilized Institute for Safe Medication Practices (ISMP) high-alert medication lists and joint patient safety reports (JPSR) per VHA Directive 1050.01(1), Quality and Patient Safety Programs, dated March 24, 2023, to establish and maintain a health care system-wide high-alert medication list. The VistA/CPRS electronic health record (EHR) may be modified to allow for local drug file alerts and other risk mitigation strategies as needed at the VA medical facility level.

b. The transition to a combined EHR requires VHA, in collaboration with DHA, to develop a core, enterprise-wide, high-alert medication list for the purpose of establishing standardized risk mitigation strategies within the EHR. VHA has identified an opportunity to standardize processes and procedures to ensure the appropriate administration, physical storage, security, accountability and inventory reconciliation of high-alert medications.

3. DEFINITIONS

a. **Authorized Personnel.** Authorized personnel are those personnel or health professions trainees who meet criteria and are approved by the VA medical facility to be granted specific permissions or perform specific duties. For purposes of this directive, these permissions/duties may include access to medication storage areas, performing medication preparation, transporting medication or administering medication.

b. **Automated Dispensing Cabinet.** An automated dispensing cabinet (ADC) is a computerized drug storage device or cabinet that electronically dispenses medications in a controlled fashion and tracks medication use. This device is also known as a unit-based cabinet (UBC), an automated dispensing device (ADD), an automated dispensing unit (ADU), or an automated dispensing machine (ADM). Manufacturer names for ADCs include Omnicell, Pyxis, AcuDose, and MedSelect, with many others commercially available.

c. **Blind Count.** Blind count is the counting of medication stock by an authorized staff member who does not know the balance.

d. **Computerized Prescriber Order Entry.** Computerized prescriber order entry (CPOE) is the system and process in place that requires ordering prescribers and practitioners to order medications or devices for patients electronically.

e. **Drug File Alert.** A drug file alert is a risk mitigation strategy in VistA/CPRS that occurs when a medication is flagged for action at the point of medication order entry or order verification. For example, a prescriber may have to enter a comment with rationale to satisfy the alert and proceed with ordering.

f. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing, and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. ***NOTE:*** *EHR comprises existing and forthcoming VA software. The purpose of this definition is to adopt a short, general term to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

g. **Health Professions Trainee.** A health professions trainee is an individual appointed under 38 U.S.C. §§ 7405 or 7406 who is participating in clinical or research training under supervision to satisfy program or degree requirements. Health professions trainee is a general term to describe undergraduate, graduate and continuing education students; interns, residents, fellows and VA advanced fellows; and pre-and post-doctoral fellows who spend all or part of their clinical training experiences at VA medical facilities. Some health professions trainees may be in non-clinical training fields but train in patient areas or use VA patient records or data in their training. ***NOTE:*** *Please see VHA Directive 1400.01, Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents, dated November 7, 2019, and VHA Handbook 1400.04(1), Supervision of Associated Health Trainees, dated March 19, 2015.*

h. **High-Alert Medication.** High-alert medications are medications, medication classes, or medication categories that are associated with the highest risk of morbidity and mortality when inappropriately dosed, administered or monitored. Although mistakes may or may not be more common with these drugs, the consequences of an error are typically more harmful to patients than those for other medications.

i. **Independent Double Check.** Independent double check (IDC) (also known as "witness") is a process that occurs prior to medication administration in which two licensed health care clinicians, alone and apart from each other, check and then compare results for each component of the medication order, ensure clinical appropriateness in the context of the patients plan of care, and verify the pump settings, as applicable. ***NOTE:*** *The most critical aspect is to maximize the independence of the double check by ensuring that the first health care professional does not communicate what they expect the second health care professional to see, which would create bias and reduce the visibility of an error. An IDC is performed by clinicians with training for that medication based on competency or licensure (e.g., an IDC for chemotherapy is*

performed by two licensed health care clinicians with competencies to support chemotherapy treatment).

j. **Licensed Health Care Clinician.** For purposes of this directive, a licensed health care clinician (or health professions trainee under the supervision of a licensed health care clinician) has the training and competency required to administer high-alert medications.

k. **Medication Administration Time Out.** A medication administration time out is an uninterrupted, deliberate pause in activities to focus on ensuring the seven rights of medication administration are completed (see paragraph 3.m).

l. **Order Set (VistA/CPRS) or Power Plan (Oracle Health).** An order set or power plan is a set of orders that are routinely issued by a provider in recurring situations in the care of patients with particular diseases or other conditions requiring medical, surgical, and nursing care. The consistent use of order sets is intended to reduce the risk of error, increase patient safety, improve outcomes, and increase efficiency.

m. **Seven Rights of Medication Administration.** The seven rights of medication administration check seven factors for accuracy to ensure safe medication administration. These factors are:

(1) Right Patient: ascertaining that a patient being treated is, in fact, the correct recipient for whom medication was prescribed. Identity must be confirmed using two forms of identification.

(2) Right Medication: ensuring that the medication to be administered is identical to the drug name that was prescribed.

(3) Right Dose: ensuring that the medication strength and dosage are identical to what was prescribed.

(4) Right Route: ensuring that the medication is administered via the route prescribed and is appropriate for the prescribed medication.

(5) Right Time: administering medications at a time that was intended by the prescriber and within policy for acceptable medication administration times.

(6) Right Reason: ensuring that the medication is given for the correct reasons.

(7) Right Documentation: recording each medication after dose is administered and documenting any reactions, especially atypical reactions.

n. **Smart Infusion Pump.** Smart pump infusion pump is an infusion pump with integral computer software that is, at a minimum, capable of: (1) maintaining a drug library of standard drug concentrations, which supports dose calculations and alerts the user to incorrect orders, calculation errors, or programming errors that could result in inappropriate delivery of a drug, electrolyte, or other fluid; and (2) capturing

administrative infusion data in a systematic, objective manner to support improvement in medication use. If the programmed dose is outside the preset limits, the pump alerts clinicians and can either require confirmation before beginning delivery (soft limit) or not allow delivery at all (hard limit).

o. **Weight-Based Dosing.** Weight-based dosing is the dose in metric amount per kilogram per dose or body surface area per dose (or unit of time).

p. **Tall Man Lettering.** Tall man lettering or 'selective capitalization' is the practice of writing part of a drug's name in upper case letters to help distinguish sound-alike, look-alike drugs from one another to avoid medication errors (e.g., DOButamine, DOPamine). ***NOTE:*** *Not all medications with approved tall man lettering are designated as high-alert medications.*

4. POLICY

It is VHA policy that all VA medical facilities will implement the standardized core VHA/DHA High-Alert Medication List that includes mandated national and recommended local risk mitigation strategies to ensure safe medication practices for Veterans.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** Under Secretary for Health is responsible for ensuring overall compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for:

(1) Ensuring that the Office of Nursing Services (ONS) and Pharmacy Benefits Management (PBM) collaborate to update this directive on a regular basis.

(2) Ensuring that there are no conflicts with other policies that address high-alert medication or medication administration.

(3) Ensuring there is a standardized process in VHA to request medications be added to the smart pump library.

(4) Ensuring the smart pump library is reviewed periodically by ONS and PBM in collaboration with other entities (e.g., other program offices), as appropriate.

(5) Supporting ONS and PBM with oversight of this directive.

(6) Ensuring all VA medical facilities use the smart pump library for high-alert medication infusion.

c. **Assistant Under Secretary for Health for Quality and Patient Safety.** The Assistant Under Secretary for Health for Quality and Patient Safety is responsible for:

(1) Providing aggregate safety reports to national program offices related to high alert medication activities upon request.

(2) Participating as part of the process of reviewing the VHA/DHA High-Alert Medication List and required risk mitigation strategies.

d. **Chief Operating Officer.** The Chief Operating Officer is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

(4) Collaborating with the Executive Director, PBM to ensure VISNs conduct ongoing monitoring and evaluation to assess compliance with this directive and corrective actions taken as appropriate.

(5) Collaborating with the Executive Director, PBM and VISN Directors to ensure VA medical facilities complete any mandatory risk assessments and determine which service line is responsible for coordinating the assessment activities.

(6) Collaborating with the Executive Director, PBM to ensure any mandatory high-alert medication risk assessment is communicated to the field.

e. **Veterans Health Administration Chief Health Informatics Officer.** The VHA Chief Health Informatics Officer for the Health Informatics Office is responsible for supporting Health Solutions Management (HSM) and Office of Nursing Informatics (ONI) with oversight as business owners of Bar Code Medication Administration (BCMA) software enabling guidance within this directive.

f. **Executive Director, Office of Nursing Services.** The Executive Director, Office of Nursing Services provides general oversight of this directive in collaboration with the Executive Director, Pharmacy Benefits Management, and is responsible for:

(1) Ensuring the collaboration between VHA, DHA and PBM to maintain the VHA/DHA High-Alert Medication List.

(2) Ensuring that ONS collaborates with PBM to update this directive on a regular basis.

(3) Ensuring that there are no conflicts with other policies that address high-alert medication or medication administration.

(4) In collaboration with the Executive Director, Pharmacy Benefits Management, creating a standardized process to request the addition of medications to the smart pump library and communicating this process to the VA medical facilities nursing leadership and VISN Chief Nursing Officers (CNO).

(5) Addressing noncompliance issues with VISN CNO and VA medical facility Associate Director for Patient Care Services (ADPCS).

g. **Executive Director, Pharmacy Benefits Management.** The Executive Director, PBM provides general oversight of this directive in collaboration with the Executive Director, Office of Nursing Services, and is responsible for:

(1) Ensuring the VA National Formulary Committee, with collaboration from ONS, DHA and National Center for Patient Safety (NCPS) representatives, reviews the VHA/DHA High-Alert Medication List and required risk mitigation strategies annually and as needed. The review is to be based on publications by ISMP, other published safety alerts, aggregate event reports, and requests submitted through VISNs from VA medical facilities, VHA national program offices or DHA. ***NOTE:*** *VISN Pharmacy and Therapeutics (P&T) Committees must evaluate and approve requests from VA medical facilities for consideration to modify the VHA/DHA High-Alert Medication List.*

(2) Ensuring that the VHA/DHA High-Alert Medication List is readily accessible. The list is posted on the VHA Pharmacy Benefits Management (PBM) SharePoint at https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/HighAlertMeds/Forms/AllItems.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(3) Ensuring new medications reviewed by the VA National Formulary Committee are evaluated for addition to the VHA/DHA High-Alert Medication List. ***NOTE:*** *For further information on the VA National Formulary Committee, see VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.*

(4) In collaboration with ONS, creating a standardized process to request the addition of medications to the smart pump library and communicating this process to the VA medical facilities pharmacy leadership.

(5) Ensuring PBM representation on any ONS or NCPS workgroups developed to review addition of medications to the smart pump drug library.

(6) Collaborating with the Chief Operating Officer to ensure VISNs conduct ongoing monitoring and evaluation to assess compliance with this directive and corrective actions taken as appropriate.

(7) Determining if high-alert medication risk self-assessments (e.g., ISMP) available from patient safety organizations are mandatory.

(8) Collaborating with the Chief Operating Officer and VISN Directors to ensure VA medical facilities complete any mandatory risk assessments and determine which service line is responsible for coordinating the assessment activities.

(9) Collaborating with the Office of the Chief Operating Officer to ensure any mandatory high-alert medication risk assessment is communicated to the field.

h. **Executive Director, Physician Assistant Services.** The Executive Director, Physician Assistant Services is responsible for communicating the contents of this directive to all program offices under their auspices.

i. **Executive Director, National Center for Patient Safety.** The Executive Director, NCPS is responsible for:

(1) Providing and facilitating aggregate event review data to the Assistant Under Secretary for Health or other program offices upon request or when issues with high-alert medications are identified.

(2) Providing and facilitating input to the Executive Director, PBM on modifications to the VHA/DHA High-Alert Medication list and required risk mitigation strategies.

(3) Facilitating VA medical facility completion of any mandated high alert medication related patient safety risk assessments (e.g., ISMP self-assessments).

j. **Executive Director, Office of Analytics and Performance Integration.** The Executive Director, Office of Analytics and Performance Integration is responsible for communicating the contents of this directive to all program offices under their auspices.

k. **Executive Director, Health Solutions Management.** The Executive Director, HSM is responsible for:

(1) Ensuring collaboration with ONI as BCMA Software co-business owner.

(2) Ensuring decisions related to devices that intersect with BCMA use with high-alert medications are made in collaboration with Executive Director, Office of Nursing Informatics.

l. **Executive Director, Office of Nursing Informatics.** The Executive Director, Office of Nursing Informatics is responsible for:

(1) Ensuring collaboration with HSM as BCMA Software co-business owner.

(2) Ensuring software requirements necessary to support this directive are in place in VHA.

(3) Ensuring risk mitigation strategies related to BCMA and high-alert medications are in place in VHA.

(4) Ensuring decisions related to devices that intersect with BCMA use and high-alert medications are made in collaboration with Executive Director, HSM.

m. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Ensuring that there is adequate staffing to comply with this directive.

(3) Ensuring any mandatory patient safety risk assessments (e.g., ISMP) are completed.

(4) Ensuring VA medical facilities have the appropriate tools to analyze their high-alert drug administration data (BCMA and IV smart pumps) to assure all patients have the benefit of both technologies.

(5) Collaborating with the Chief Operating Officer and the Executive Director, PBM to ensure VA medical facilities complete any mandatory risk assessments and determine which service line is responsible for coordinating the assessment activities.

n. **Chair, Veterans Integrated Service Network Pharmacy and Therapeutics Committee.** In addition to what is stated in VHA Directive 1108.08, the Chair, VISN P&T Committee is responsible for reviewing VA medical facility requests to amend the VHA/DHA High-Alert Medication List and, if appropriate, forwarding those requests to the VA National Formulary Committee for consideration.

o. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring VA medical facility implementation of and compliance with this directive.

(2) Ensuring the VA medical facility reconciles their existing high-alert medication list with the core VHA/DHA High-Alert Medication List and updates it within six months of the publication of this directive.

(3) Ensuring the VA medical facility evaluates ADC placement and storage of high-alert medications to meet the workflow and processes of various patient care areas and to ensure accessibility to high-alert medications at the point of care.

(4) Ensuring adequate staffing resources are available to support compliance with this directive.

(5) Ensuring BCMA is adequately resourced and established in all patient care areas where high-alert medications are administered, and processes can be accomplished with technology. ***NOTE:*** *This includes evaluating the feasibility of implementing BCMA in outpatient and procedural areas.*

(6) Conducting a risk assessment that includes mitigation strategies for medication administration in the outpatient and procedural areas where BCMA implementation is not currently feasible. ***NOTE:*** *Future EHR implementation provides expansion of BCMA to all clinical areas.*

(7) Ensuring all VA medical facilities use a standardized process to request the addition of medications to the smart pump drug library.

(8) Ensuring staff members have access to the VA medical facility High-Alert Medication List.

(9) Ensuring that all personnel working in any clinical setting and are responsible for the administration, storage, or return of high-alert medications complete the mandatory training developed for this directive (see paragraph 7).

(10) Ensuring any mandatory patient safety risk assessments (e.g., ISMP) are completed at the VA medical facility.

p. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff responsible for:

(1) Providing support for oversight of VA facility medical staff compliance with this directive.

(2) Ensuring corrective action is taken if non-compliance with this directive is identified.

(3) Ensuring staff members have completed all required role-specific training related to high-alert medications.

q. **VA Medical Facility Patient Safety Manager and/or Medication Safety Officer.** The VA medical facility Patient Safety Manager and/or Medication Safety Officer is responsible for providing, at least quarterly, a report of high-alert medication events to the appropriate committee for review (P&T, QSV, etc.).

r. **VA Medical Facility Associate Director for Patient Care Services.** The VA medical facility Associate Director for Patient Care Services (ADPCS) (who may also be called the Chief Nurse Executive) is responsible for:

(1) Providing support for oversight of Nursing personnel compliance with this directive.

(2) Ensuring corrective action is taken if non-compliance with this directive is identified.

(3) Ensuring staff have completed all required role-specific training related to high-alert medication.

(4) Ensuring the smart pump drug library is utilized for high-alert medication infusions.

(5) Evaluating on an ongoing basis the need for additional automated dispensing equipment or enhancements to existing ADC cabinets, refrigerators, printers, scanners, or software in collaboration with the VA medical facility Chief of Pharmacy Service.

(6) Ensuring the medication administration process is reviewed by the nursing staff at least annually and practices to reduce interruption during medication administration are implemented, if applicable.

(7) Ensuring that local risk mitigation strategies for newly identified medications of concern are put in place at the VA medical facility as soon as possible after analysis done according to the set facility process in collaboration with the VA medical facility Chief of Pharmacy Service.

(8) Ensuring the smart pump library is up to date.

(9) Collaborating with VA medical facility Pharmacy and Nursing to review ongoing needs/requests for smart pump library modifications.

s. **VA Medical Facility Chief of Pharmacy Service.** The VA medical facility Chief of Pharmacy Service is responsible for:

(1) Overseeing Pharmacy Service compliance with this directive and ensuring that corrective action is taken if noncompliance is identified.

(2) Reviewing the VHA/DHA High-Alert Medication List and identifying if additional local risk mitigation strategies should be used in addition to the required national strategies for specific medications.

(3) Evaluating on an ongoing basis the need for additional automated dispensing equipment or enhancements to existing ADC cabinets, refrigerators, printers, scanners, or software in collaboration with the VA medical facility ADPCS.

(4) Ensuring staff have completed all required role specific training and related to high-alert medications.

(5) Ensuring the pharmacy service has a local defined process related to stocking high-alert medications (at minimum) at off-site locations such as Community Outpatient Clinics (CBOCs) or Community Living Centers (CLCs). The process includes review and approval of what high-alert medications (at a minimum) will be stocked in offsite locations and establishes a chain of custody and verification of receipt for the transfer of high-alert medications to and from outlying VA medical facilities.

(6) Collaborating with Nursing to review ongoing needs/requests for addition of medication/doses to the smart pump library for presentation to the VA medical facility

P&T Committee for review and approval or defer to the national process once established.

(7) Ensuring that local risk mitigation strategies for newly identified medications of concern are put in place as soon as possible at the VA medical facility after analysis done according to the set facility process in collaboration with the VA medical facility ADPCS.

t. **VA Medical Facility Pharmacy and Therapeutics Committee.** The VA medical facility P&T Committee, or a similarly authorized and interdisciplinary body, is responsible for:

(1) Reviewing, at least quarterly, medication related events and close calls reported to any drug related adverse events (e.g., JPSR, VA Adverse Drug Event Reporting System (ADERS)). See VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020, for additional details.

(2) Reviewing, at least quarterly, smart pump reports and data for high-alert medications as part of quality improvement. Examples of smart pump reports for review are the Continuous Quality Improvement (CQI) reports from the infusion device, and high-alert medication events from JPSR.

(3) Reviewing, at least annually, medications with a high frequency of facility level adverse events related to ordering, storage or administration.

(4) Reviewing on an ongoing basis any newly published medication safety related guidance (e.g., ISMP, Joint Commission Sentinel Event Alerts, Food and Drug Administration (FDA), Patient Safety Alerts, Advisories and Notices).

(5) Facilitating an annual review of the VA medical facility high-alert medication list which includes reconciling the list with the VHA/DHA High-Alert Medication list and identifying risk mitigation strategies to be used locally in addition to the required national strategies.

(6) Forwarding facility requests to amend the VHA/DHA High-Alert Medication List to the VISN P&T Committee.

u. **VA Medical Facility Nursing Staff.** VA medical facility nursing staff members are responsible for:

(1) Completing required role-specific training related to high-alert medications.

(2) Performing an IDC as outlined in this directive prior to administering a high-alert medication.

(3) Ensuring designated high-alert medications are labeled, when applicable.

v. **VA Medical Facility Licensed Health Care Providers (or Health Professions Trainees).** VA medical facility licensed health care providers or health professions trainees are responsible for:

(1) Administering high-alert medications, when clinically indicated, using order sets or power plans via EHR whenever possible.

(2) Completing required role-specific training related to high-alert medications. In the case of trainees, this is accomplished by taking the Mandatory Training for Trainees course.

w. **VA Medical Facility Pharmacy Staff.** VA medical facility pharmacy staff is responsible for:

(1) Providing high-alert labeling for designated high-alert medications, when applicable.

(2) Completing role-specific training related to high-alert medications.

x. **VA Medical Facility Health Care Technology Management.** The VA medical facility Health Care Technology Management is responsible for:

(1) Collaborating with VA medical facility Pharmacy and Nursing to update the smart pump library as required in VA medical facilities without reliable Wifi capability.

(2) Ensuring issues with IV smart pump hardware and firmware are resolved in a timely manner.

6. ADMINISTRATION OF HIGH-ALERT MEDICATIONS

a. **Authorized Administrators.**

Only licensed health care clinicians may administer (or delegate administration of) high-alert medications within the scope of their license, privileges and VHA guidance. Additional guidance is provided in Appendix B and VHA Patient Safety Alert (Alert ID: AL22-02): Unlicensed Assistive Personnel (UAP) are prohibited from administering medications via high-risk routes of Intra-arterial and Intra-coronary, except for radiographic contrast, saline, and heparin flushes in support of radiographic contrast administration, dated January 3, 2022. http://vaww.ncps.med.va.gov/Guidelines/alerts/index.html. ***NOTE:*** *This is an internal VA website that is not available to the public.*

b. **Independent Double Check (IDC).**

(1) High-alert medications requiring IDC are indicated in the VHA/DHA High-Alert Medication List.

(2) When using an infusion device for administration of a high-alert medication requiring IDC, perform an IDC as directed in the VHA/DHA High-Alert Medication List.

(3) During the IDC for an infusion, one licensed clinician readies the solution and a second licensed clinician, using the order in the EHR and available technology (e.g., integrated Smart Infusion Pumps, BCMA technology), independently verifies the following before starting the infusion:

(a) Patient.

(b) Drug/solution.

(c) Drug concentration.

(d) Rate of infusion.

(e) Tubing is traced by hand from the solution container to the pump and then to the patient for verification of the proper pump/channel and route of administration.

(f) Channel selection (for multi-channel pumps). ***NOTE:*** *Accurate tubing to pump connection and channel selection requires manual verification by a licensed clinician even if technology is employed to verify other elements*.

(4) An IDC occurs during all hand-off communications for patients receiving IV or epidural high-alert medication infusions. The patient, drug/solution, drug concentration, rate of infusion, line and pump attachment, and channel selection are verified.

(5) In procedural areas, those practitioners who have procedural clinical privileges or scopes of practice in anesthesia granted by the VA medical facility may, in place of an IDC, utilize processes which accommodate the specific clinical setting requirements and support safe medication administration. Suggested practices include:

(a) Purchase pre-labeled syringes in doses appropriate to a single patient so that every syringe is labeled and bar coded in a ready to administer form, when possible.

(b) Provision of pre-drawn syringes from the operating room (OR) pharmacy or inpatient pharmacy.

(c) Purchase of pre-mixed bags for infusions of drugs that are available and stable in a diluted state (e.g., norepinephrine) which minimizes compounding errors and assures that all products are safely labeled, when possible.

(d) Implementation of ADC technology to support medication use activity directly in the procedure room.

(6) In those areas not staffed by anesthesia, the VA medical facility develops structured processes and strategies for safe medication administration. ***NOTE:*** *See suggested practices in paragraph 6.b.(5).*

(7) In emergency situations, it is understood that a licensed health care clinician may not be able to complete an IDC for a designated high-alert medication.

(8) In remote locations with limited clinical staff, IDC via a remote process may be used.

(9) Where the capability exists, the IDC is documented using BCMA/EHR functionality. If BCMA/EHR functionality is not available, the IDC and witness is documented according to the VA medical facility process.

c. **Uninterrupted Medication Administration.**

(1) All VA medical facilities review, at least annually, the medication administration process and implement local practices to reduce interruption during medication administration. This includes the process from obtaining the medication to administration and medication storage configuration (e.g., cabinet location, lighting).

(2) Optional practices to reduce interruption during medication administration include but are not limited to the following:

(a) Communication devices are placed in “do not disturb” mode. Non-essential communications and activities are ceased.

(b) ADCs should be strategically placed in locations that facilitate medication administration workflow.

(c) Number of staff in the medication room (area) is limited to decrease distractions.

(d) Use of a medication “time out” (see paragraph 3.k.).

(e) Visual reminders to limit distractions/interruptions such as vests, signs, red tape, etc.

7. TRAINING

a. High-alert medication training developed by ONS and VHA PBM is required for all staff who administer, dispense, or stock high-alert medications.

b. The required training is TMS Course Number 131013789*. **NOTE:** Per VHA Directive 1052, Appropriate and Effective Use of VHA Employee Mandatory and Required Training, dated June 29, 2018, required TMS courses for health professions trainees may only include VHA Mandatory Training for Trainees (TMS ID 3185966) or VHA Mandatory Training for Trainees –Refresher (TMS ID 3192008). All required training for trainees must be inserted into these Mandatory Training for Trainees courses.*

8. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

9. REFERENCES

a. 38 U.S.C § 7301(b).

b. VHA Directive 1050.01(1), Quality and Patient Safety Programs, dated March 24, 2023.

c. VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020.

d. VHA Directive 1108.01(2), Controlled Substance Management, dated May 1, 2019.

e. VHA Directive 1108.07(1), General Pharmacy Service Requirements, dated November 28, 2022.

f. VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.

g. VHA Directive 1052, Appropriate and Effective Use of VHA Employee Mandatory and Required Training, dated June 29, 2018.

h. VHA Directive 1400.01, Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents, dated November 7, 2019.

i. VHA Handbook 1400.04(1), Supervision of Associated Health Trainees, dated March 19, 2015.

j. VHA Patient Safety Alert (Alert ID: AL22-02): Unlicensed Assistive Personnel (UAP) are prohibited from administering medications via high-risk routes: Intra-arterial and Intra-coronary, except for radiographic contrast, saline, and heparin flushes in support of radiographic contrast administration, dated January 3, 2022: http://vaww.ncps.med.va.gov/Guidelines/alerts/index.html. ***NOTE:*** *This is an internal VA website that is not available to the public.*

VETERANS HEALTH ADMINISTRATION (VHA)/DEFENSE HEALTH AGENCY (DHA) HIGH-ALERT MEDICATION LIST: DETERMINING HIGH-ALERT MEDICATIONS

1. VHA Pharmacy Benefits Management (PBM) and Office of Nursing Services (ONS), working with other stakeholders, are responsible for establishing a standard process for determining medications deemed 'high-alert' and the minimum standard risk mitigation strategies VA medical facilities must implement.

2. The VHA/DHA high-alert medication will be determined based on:

a. Potential for high-alert designation based on evidence when new drug or drug class is added to the shared drug file or evaluated for formulary addition.

b. Requests from DHA leadership and VHA Veterans Integrated Service Networks (VISNs).

c. Institute for Safe Medication Practices (ISMP) High-Alert medication lists and other related publications such as drug safety event reports. Some resources can be found:

(1) ISMP High-Alert Medications in Acute Care Settings, dated August 23, 2018, available at https://www.ismp.org/.

(2) ISMP High-Alert Medications in Long-Term Settings, dated May 20, 2021, available at https://www.ismp.org/.

(3) ISMP High-Alert Medications in Community/Ambulatory Settings, dated August 23, 2018, available at https://www.ismp.org/.

d. Local medication event reports, root cause analyses (RCA), and other quality reports provide information for potential hazards on an ongoing basis. In addition, the joint patient safety reports (JPSR) program has pre-built reports for high-alert medication event review.

3. VA medical facilities must maintain a high-alert medication list that includes medications from the core VHA/DHA High-Alert Medication list that they currently stock and any medications identified as high-alert at the local level.

VA medical facilities will forward requests for modifications to the VHA/DHA High-Alert Medication List through their VISN P&T Committee via their facility Pharmacy and Therapeutics (P&T) Committee. This may be a request to add or remove a medication or route of administration or a request to add or remove a required risk mitigation strategy.

ADMINISTRATION OF HIGH-ALERT MEDICATIONS

1. High-Alert Medication Administration Procedure.

a. Licensed health care clinicians administering high-alert medications follow the seven rights of medication administration.

b. Changes to route, order, or dose of a high-alert medication (e.g., medication orders with titration parameters) require review of the seven rights of medication administration with each change.

c. When infusions of high-alert medications are started, reconnected, changed (new bag or syringe), or the rate is adjusted, the tubing is traced by hand from the solution container to the pump and then to the patient for verification of the proper pump/channel and route of administration.

d. When infusing high-alert medications along with other intravenous (IV) infusions, the drug name will be readily identifiable on the IV pump and on the IV tubing at the point closest to the patient.

e. High-alert medication infusions are connected to the administration set or a manifold device below the electronic infusion pump controlling a primary or carrier IV fluid. A separate pump is used to control the rate of the infusion (i.e., high-alert medication infusions are not administered using the "secondary IV" procedure on the administration pump).

f. The smart pump drug library is utilized for all high-alert medication infusions.

2. Bar Code Medication Administration (BCMA) Technology.

a. BCMA technology is used for all high-alert medication administration when available.

b. This serves as an electronic verification when the manufacturer barcode is scanned on the medication being administered. An independent double check may be required with specific medications and their routes of administration (see VHA/DHA High-Alert Medication List).

c. Areas that do not utilize BCMA technology implement evidence-based safeguard practices when administering high-alert medications. Examples may include but are not limited to:

(1) Medication administration “time out”

(2) Independent double check

(3) Standardization (e.g., standard concentrations, checklists, approved medication order sets)

3. Smart Pumps.

a. Intravenous pumps with automated alerts and drug error reduction software, or smart pumps with soft stops/limits and hard stop/limits activated are used to infuse high-alert medications, where available.

b. When an infusion device with prebuilt infusion parameters is used and pre-set infusion parameters are not available for a high-alert medication (e.g., the medication is new and not yet added to the library), an IDC of the medication parameters programmed into the pump occurs prior to initiation of the infusion.

c. Where/as much as possible, use multi-channel infusion pumps for a single patient for the simultaneous delivery of therapies by the same route (e.g., IV and epidural infusions are NOT infused on the same individual pump).

AUTOMATED DISPENSING CABINETS

1. Automated Dispensing Cabinet (ADC) connectivity and configuration.

a. ADCs are configured to receive and display admission, discharge, and transfer information including the patient's name and a secondary identifying factor (e.g., date of birth, medical record number, social security number). Temporary patient entries into the ADC database are discouraged and must be reviewed by the unit nursing supervisor or designee for appropriateness at least weekly.

b. The ADC, except for anesthesia carts and ADCs in procedural areas, are configured to display a profile of active medication orders under each patient (e.g., in the electronic health record (EHR), active inpatient and clinic orders would display on the cabinet profile). Medications are removed by accessing the patient's profile and documenting the drug(s) and quantity removed from the ADC. ***NOTE:*** *Medications may not appear in the patient profile in areas such as the emergency department where there may be a delay in medication order verification due to urgency.*

c. The cabinet's database must be configured to require at least a 5-letter medication name entry.

d. When possible, the cabinet's database must be configured with tall man lettering for high-alert medications (e.g., DOBUTamine and DOPamine). The Veterans Health Administration (VHA)/Defense Health Agency (DHA) High-Alert Medication List indicates the high-alert medications where tall man lettering is required.

e. Where the capability exists, high-alert medications must be distinguished from other medications in the cabinet database (e.g., **Insulin, Aspart, 100 units/mL** or a pop-up alert).

f. High-alert medications stored in the ADC must be in the most ready-to-administer form whenever possible. If multidose products must be stocked, the stock bottle(s) must be secured in a locked storage drawer or bin when not in use.

g. Within the ADC, medications must be stored in locked, lidded drawers, when possible.

h. When initially stocking an ADC, the medication or solution must be scanned to ensure the correct medication is being stocked.

i. If the technology is available, medication not used during a procedure may be returned to a lidded drawer if it is scanned prior to return to the ADC. Otherwise, high-alert medications are not restocked to the ADC by the end-user and unused medication must be returned to a one-way return bin, locked cabinet, or other method to secure medication prior to return to pharmacy.

j. At minimum, areas without Bar Code Medication Administration (BCMA) deployed must scan high-alert medications upon removal from ADCs or refrigerators, when accessed via override or from open/multiple dose matrix drawers.

2. ADC Reporting and Oversight. The VA medical facility must establish a process for the ongoing review of the following reports at least quarterly. The results of these reviews will be reported to pharmacy and nursing supervisory personnel (pharmacy/nurse committee or equivalent). While there are a variety of ADC systems in use throughout the enterprise and there may be variations in report names, the monitoring report for the described cabinet activity should be used.

a. **ADC Level Discrepancy Report.** Following local VA medical facility policy, the ADC level discrepancy report is reviewed for high-alert drugs identified as requiring a blind count. As part of the hand-off procedure all discrepancies are reconciled prior to resolving in the cabinet. If a discrepancy cannot be reconciled, it is referred to supervisory personnel for further investigation and action.

b. **Temporary Patient Entry Report.** According to local procedures all temporary patient entries who have high-alert medications removed under their name should be reviewed and high-alert medication removal reconciled with the documentation in the EHR for the activity performed under the temporary entry. Temporary patient entry cases that cannot be reconciled are referred to supervisory personnel for further investigation.

c. **Medication Profile Override Report.** The medication profile override report is reviewed for high-alert medications. High-alert medications removed via override are reconciled with an order. ***NOTE:*** *In procedural areas, high-alert medications may be reconciled with procedural documentation.*

d. **Null or Cancelled Cabinet Activity Report.** The null or cancelled cabinet activity report showing instances of cabinet access without any apparent high-alert medication removal is reviewed in conjunction with the discrepancy report.

e. **BCMA to Dispensing Cabinet Routine.** If available, use the BCMA to Dispensing Cabinet Routine to reconcile cabinet removals with BCMA administration for all high-alert medications. Cabinet medication removal that cannot be accounted for in BCMA should be referred to a supervisor for further action. ***NOTE:*** *The BCMA to Dispensing Cabinet routine is class 2 software installed at some VA medical facilities. This directive does not require facilities to procure such a program.*

REDUCING POTENTIAL FOR ERRORS

1. National Risk Mitigation Strategies. Nationally mandated risk mitigation strategies have been assigned to specific high-alert medications in the Veterans Health Administration (VHA)/Defense Health Agency (DHA) High-Alert Medication List. These risk mitigation strategies are required to be implemented and cannot be altered at the Veterans Integrated Service Networks (VISN) or Department of Veterans Affairs (VA) medical facility level:

a. Independent double check (IDC)

b. Tall man lettering (or selective capitalization): In cases where high-alert medications are also look-alike or sound-alike to other medications, tall man lettering is used in EHR, where possible, and based on the Food and Drug Administration (FDA) and Institute for Safe Medication Practices (ISMP) recommended tall man lettering list. That list can be found at the following link: https://www.ismp.org/recommendations/tall-man-letters-list.

High-alert medications that are added to the VA formulary are reconciled with the tall man lettering recommendations from the FDA or ISMP list.

c. Physical auxiliary labels are used as a precaution, where possible, to reduce errors in storage and dispensing.

d. Auxiliary high-alert labeling: High-alert medications that require a high-alert label affixed to the product are found in the VHA/DHA High-Alert Medication List. This additional labeling information is included on the medication order label, affixed as an auxiliary label by pharmacy prior to delivery to the ward, unit, or clinic or may be included as part of the extemporaneous packaging.

e. Blind count: A method of physical inventory taken by a health care practitioner who performs a hands-on count of inventory without knowledge of or access to the quantities currently shown in electronic or other inventory systems. High-alert medications that require a blind count are found on the VHA/DHA High-Alert Medication List.

2. Local Risk Mitigation Strategies. VA medical facilities may implement additional risk mitigation strategies if deemed necessary or appropriate. Local risk mitigation strategies are standardized methods for reducing risk of patient harm. Select medications on the VHA/DHA High-Alert medication list have mandated local mitigation strategies as these are deemed essential for patient safety. They are mandated for enterprise-wide application. VA medical facilities are encouraged to use a collaborative approach to evaluate the use of local risk mitigation strategies for improving medication safety. Local risk mitigation strategies include:

a. **Drug file alert.**

b. **Physical separation.** A fixed partition, divider, or designated location is used to create a deliberate detachment or division among different medications. This includes refrigerated and non-refrigerated medications that are kept apart from other medications or are isolated in a rapid intubation kit or lidded box/drawer wherever they are stored in the facility.

c. **Unit dose/premade solution purchasing.** Whenever possible, VA medical facilities provide high-alert medications in the most readily available form. Medications are purchased in single doses, when available, to preclude the need for repackaging, sterile compounding, or administration of a partial dose.

d. **Restricted ordering/administration.** These high-alert medications may only be ordered by a licensed health care clinician who has the expertise and training in the required dosing and monitoring parameters. Care should be taken to include interim mitigation strategies for contingency/downtime procedures for all strategies that rely on software solutions.

e. **Monitoring oversite/dashboard.** Potential adverse events, dosing errors, needed monitoring, or other relevant data are collected and acted upon by a designated individual, service line, or work group. For example, Smart Infusion Pump reports, the PBM Medication Use Evaluation Tool (MUET), direct-acting oral anticoagulants (DOAC) dashboard and the clinical informatics reports on anticoagulants, or the joint patient safety reports (JPSR) high-alert medication report.

f. **Smart pump library.** Medication may only be administered according to parameters set within the National Smart Pump library. ***NOTE:*** *This applies to Oracle Health sites only. VISNs or VA medical facilities are able standardize solutions to the 'Standardized for Safety Initiative' in the interim located at: https://www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Adult-Infusion-Standards.pdf.*

g. A variety of other tools should be considered for use such as:

(1) Improving access to information about these medications (e.g., dose calculation tables).

(2) The provider orders high-alert medications using standardized electronic order sets whenever possible.

(3) ADC dispensing alerts.

(4) Labeling of the ADC pockets.

3. Storage and Inventory of High-Alert Medications.

a. VHA physical security requirements and options for pharmacy drug storage rooms are outlined in VA Directive 0730/4, Security and Law Enforcement, dated March 29, 2013.

b. High-alert medications stored outside of pharmacy must be stored in Automated Dispensing Cabinets (ADC) or medication cart with access controls. If the high-alert medication does not fit into the ADC or medication cart, then it must be stored in a designated storage area (e.g., locked cabinet) with personally identifiable electronic access controls so that only authorized personnel have access to the medication. ***NOTE:*** *Code carts are secured and monitored according to VA medical facility processes. Emergency high-alert medications (e.g., rapid intubation kits) are stored in locked areas using an approved tamper evident mechanism (e.g., security tag locks) and monitored per VA medical facility processes.*

c. When unauthorized personnel require access to these medication storage areas, they must be accompanied by authorized personnel (e.g., authorized personnel must be present with environmental services requiring access to clean, or engineering requiring access to repair equipment).

d. Refrigerators that store high-alert medications must be locked. If it is not possible to lock the refrigerator, then a locked bin must be used to store high-alert medications in the refrigerator. Refrigerated high-alert medications must be organized in storage containers secured to the refrigerator and using visual management to prevent incorrect product selection.

e. The ADC must be programmed to require an inventory verification (blind count) for designated high-alert medications when they are accessed. High-alert medications requiring inventory verification may be found at: https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/HighAlertMeds/Forms/AllItems.aspx. Any discrepancies discovered during this process are investigated and reconciled prior to resolving in the cabinet. Suspicious activity is referred to the area supervisor and, if necessary, the VA Police for further action.

f. VA medical facilities may designate select non-controlled high-alert medications (such as propofol) to be added to the ADC using the “Witness Required” function or equivalent. The “Witness Required” function requires a verifier when stocking the ADC. A Registered Nurse (RN), Licensed Practical Nurse (LPN), or other authorized staff member must verify the medication and the appropriate level at the ADC via the “Witness Required” function during the pharmacy inventory restock.

g. For VA medical facilities with pharmacies that are not operational 24/7 but emergent access to high-alert medications is needed, then those medications may be stored in an ADC, night cabinet, or a section of the pharmacy with controlled access and separate from the main pharmacy area.

RETURN OF HIGH-ALERT MEDICATIONS

1. Medications that must be returned to pharmacy are secured as required by VHA Directive 1108.07(1), General Pharmacy General Service Requirements, dated November 28, 2022, and VA Handbook 0730/4, Security and Law Enforcement, dated March 29, 2013. VA medical facilities may use ADCs, locked cabinets, one-way return bins or other methods to secure and limit access to medications held for return to pharmacy.

2. If part of a medication, prepared for administration, is unused then the medication is disposed of per VA medical facility processes.

TRANSPORTING HIGH-ALERT MEDICATIONS TO OUTLYING VA MEDICAL FACILITIES

1. Medications are packaged and secured for transport using tamper-evident packaging. Medications may be shipped overnight to the VA medical facility's clinic administrator or designee.

2. In addition to this directive, the requirements for transferring controlled substances between Drug Enforcement Administration (DEA) registrants are found in VHA Directive 1108.01(2), Controlled Substance Management, dated May 1, 2019.

3. VHA Directive 1108.07(1), General Pharmacy Service Requirements, dated November 28, 2022, requires local policy when transporting medications to a home health setting.

UPDATE TO VA MEDICAL FACILITY LIST OF HIGH ALERT MEDICATIONS TO ENSURE PATIENT SAFETY

1. Guidance. The purpose of this appendix is to consolidate guidance on the Enterprise List for High Alert Medications and request incorporation into Department of Veterans Affairs (VA) medical facility lists of High Alert Medications to ensure patient safety. Veterans Health Administration (VHA) Directive 2013-006, The Use of Unlicensed Assistive Personnel (UAP) in Administering Medication, dated March 5, 2013, requires all VA medical facility Directors to ensure drugs for medication administration by the UAP may not include medications contained on the VA medical facility's list of High Alert Medications.

2. Background.

In May 2021:

a. All VA medical facilities were requested to update and verify their list of High Alert Medications to include all drugs listed on the VHA National High Alert Drug Classes, located at the following link: https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/HighAlert%20Meds/Forms/AllItems.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.* Thereafter, VA medical facilities shall verify monthly updates to the Enterprise List for High Alert Medications and ensure they are incorporated into their VA medical facility list of High Alert Medications.

b. Veterans Integrated Service Networks (VISN) Directors were requested to attest to their respective VA medical facilities' assurance that UAPs are not administering any High Alert Medications located on the Enterprise List for High Alert Medications.