INPATIENT PHARMACY SERVICES

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides specific direction and procedures related to the appropriate storage, handling, and dispensing of medications and supplies for VHA medical center inpatients.

2. SUMMARY OF MAJOR CHANGES. This VHA Handbook incorporates updates to the previous Manual M-2, Part VII, Chapter 3, new United States Pharmacopeia (USP), Chapter <797> requirements for sterile products, new guidelines for automated pharmacy systems, and Health Insurance Portability and Accountability Act (HIPAA) of 1996 requirements.

3. RELATED DIRECTIVE. VHA Directive 1108 (to be published).

4. RESPONSIBLE OFFICE. The Chief Consultant, Pharmacy Benefits Management Strategic Health Group (119) is responsible for the contents of this Handbook. Questions may be addressed to (202) 273-8429.

5. RECISSIONS. VHA Manual, M-2, Part VII, Chapter 3, Inpatient Services, dated July 20, 1995, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on, or before, the last working day of June 2011.

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INPATIENT PHARMACY SERVICES

1. PURPOSE

This Veterans Health Administration's (VHA) Handbook provides specific direction and procedures related to the appropriate handling and dispensing of all medications and medication-related ancillary products to inpatients.

2. AUTHORITY

The Pharmacy Service must be in compliance with relevant standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); the practice standards, guidelines, and technical bulletins of the American Society of Health System Pharmacists (ASHP); and the United States Pharmacopeia (USP) Chapter <797> (entitled "Pharmaceutical Compounding – Sterile Preparations); and requirements of the Health Insurance Portability and Accountability Act (HIPAA) as they pertain to patient privacy. The Department of Veterans Affairs (VA) follows all applicable Federal and state laws (where adopted) and regulations concerning the dispensing of medications to hospitalized patients.

3. SCOPE

The scope of this Handbook encompasses the medication management systems utilized for all inpatients and, where applicable, to other bed services (i.e., same-day-surgery, hemodialysis units, etc.) in VA medical facilities.

4. RESPONSIBILITY OF CHIEF, PHARMACY SERVICE

The Chief of Pharmacy Service is responsible for:

a. The provision of a safe medication management system.

b. The utilization of Veterans Health Information Systems and Technology Architecture (VistA) applications for all information management.

c. A planned and systematic monitoring program to evaluate, on an annual basis, the quality and the appropriateness of pharmacy services in regard to the medication use process. ***NOTE:*** *This monitoring and evaluation program is an integral part of the overall Performance Improvement Program of the medical center.*

d. Adequate staffing and space, as defined by existing criteria, provided for inpatient medication distribution, and clinical and administrative programs.

e. Clean, orderly, well-lit, free of clutter, distraction, and noise workspaces where medications are prepackaged.

f. Ensuring the provision of ongoing educational activities and the competency of all pharmacy professional, technical, and ancillary support staff.

g. Disposing of all patient-specific information as soon as possible in a manner to ensure privacy.

h. Ensuring that Pharmacy Service provides adequate direction for the receipt, distribution, control, accountability, and quality of medications used throughout the medical center.

i. Ensuring that an annual assessment is conducted of the processes used throughout the medical center for compounding sterile medications, consistent with established standards and best practices.

5. MEDICATION MANAGEMENT SYSTEMS

a. **Unit-Dose Drug Distribution System.** A unit-dose drug distribution system, which permits identification of the drug up to the point of administration, must be the primary distribution system for all inpatient areas. Medications dispensed are to be contained in single unit packages and dispensed in ready-to-administer forms, when possible. The exceptions are patients authorized for self-medication in select bed sections (see VHA Handbook 1108.3 Self Medication Program).

b. **Automatic Replenishment Drug Distribution System.** The automatic replenishment drug distribution system is one in which medications are prepackaged in an amount, or volume, consistent with established par levels. These medications are dispensed in the most ready-to-administer forms available from the manufacturer, or if feasible, in unit-doses that have been repackaged by the pharmacy or licensed repackager.

6. ADMINISTRATION OF THE MEDICATION MANAGEMENT SYSTEMS

The Chief of Pharmacy Services, or designee, must ensure that:

a. All medication orders are reviewed by a licensed pharmacist prior to the administration of the drug, except when required for emergent need where all processes are controlled by a licensed independent practitioner (LIP). In those instances where a prior review is not possible, the pharmacist must review the order as soon as possible (within 24 hours) in accordance with JCAHO requirements.

b. Orders are dispensed for individual patients up to a 24-hour period. In the case of nursing home care units (NHCU), or long-term units, quantities in excess of a 24-hour supply may be issued (i.e., 48 hours, 72 hours, or up to 30 days when a cardex system is utilized), if appropriately packaged. Cart-less systems meet the intent of this requirement and are considered unit-dose medication supply systems.

c. Standardized administration times and response times for first doses are to be established in local medical center policy to ensure the timely administration of medications. Off-schedule

dispensing of "STAT," "NOW," and change orders must be addressed in local medical center policy.

d. Bar-coded medications are delivered to the inpatient units at scheduled times and in suitable containers that fully identify the patient. When point-of-care delivery systems (i.e., Pyxis, Omnicell, AcuDose, etc.) are used, patient profiling interfaces are required.

e. If local medical center policy permits the use of starter packs or sample medications, these items are controlled and dispensed by Pharmacy Service, and meet all applicable medication management standards; all prepackaging and repackaging of unit doses must have the appropriate packaging records.

f. The VistA Automatic Replenishment system is utilized to record usage data including the unit or clinic, the item(s) provided, and the quantities provided as the record of inventory accountability. Pharmacy personnel maintain and utilize these computer records for inventory accountability.

g. Stock levels consistent with the needs of the using unit or clinic are established by pharmacy, unit and/or clinic personnel.

h. All prepackaged units contain the name of the medication, its formulation (i.e., tablet, capsule), strength, lot number, barcode, and expiration date.

i. Appropriate prepackaging records, such as the VA Form 10-1362, Pharmacy Service Prepackaging Record or the electronic equivalent, is maintained to ensure complete identification in the case of a drug recall or other need for validation. These records are to be retained for a period of three years.

j. Only pharmaceutical items are permitted in medication storage refrigerators. Medication refrigerator temperature monitoring must be handled according to local medical center policy.

k. Commercially available sterile product solutions are bar-coded and available on nursing care units as stated in local medical center policy. Those admixtures requiring storage at reduced temperatures are to be placed in the designated medication refrigerators.

l. All approved medication storage areas (including pharmacy storage areas) are inspected by Pharmacy personnel every 30 days and in accordance with all applicable standards. ***NOTE:*** *Storage of medication in areas other than approved locations is not authorized.*

7. AUTOMATED PHARMACY SYSTEMS

a. “Automated Pharmacy Systems” include, but are not limited to, mechanical systems that perform operations or activities (other than compounding or administration) relative to the storage, packaging, dispensing, or distribution of medications. These systems may collect, control, and maintain all transaction information.

b. Automated pharmacy systems must be utilized by Pharmacy Service to improve efficiency and accuracy.

c. Pharmacy service must establish written policy and procedures to assess workflow, establish training programs, and standardize the use of the equipment to include minimum competency requirements for all personnel who have access to, and operate the equipment. The use of automated pharmacy systems requires written policy and procedures in place prior to their installation to ensure safety, accuracy, security, and patient confidentiality. This policy must define access limits to the equipment and medications.

d. Automated pharmacy systems must include a standardized Health Level 7 (HL-7) interface to the VistA system.

e. Pharmacy service must establish performance requirements for the manufacturer, pharmacy service personnel, and the automated pharmacy system during and after implementation, including installation, workflow assessment, maintenance, and training.

f. Pharmacy Service must develop a plan for ensuring safe and efficacious use of the system(s) with a focus on patient safety. The plan needs to identify the minimum standards that are routinely assessed through an established monitoring and quality assurance program. The plan needs to address high-risk drugs, medication errors, and controlled substance discrepancies.

g. Pharmacy Service must establish a contingency plan in the event of a system, power, or process failure. This plan needs to include who is contacted when the system is down and how medications stored in the system are to be secured and/or obtained. It is recommended that a system be established to determine how to recognize when a system failure occurs or is imminent; how to compensate to protect patient safety when failures occur; and how failures are to be corrected expeditiously.

h. Pharmacy Service must ensure that patient confidentiality is maintained in accordance with HIPAA standards. Safeguards must be established to prevent "outside" access to patient data.

i. Pharmacy Service must implement an ongoing quality assurance program that monitors performance of the automated pharmacy system. Standards and required documentation must be included in local policies and procedures. ***NOTE:*** *See subparagraphs 17b, 17e, and 17g for sources of standards.*

8. MEDICATION BROUGHT INTO MEDICAL CENTER BY PATIENTS

a. A process must be established to safely control, or manage, medications brought into the medical centers by patients or family members. Local medical center policy must provide guidance as to the disposition, storage, or destruction of these medications.

b. For those facilities that allow patients to bring non-VA medications(s) into the medical center, these medications must not be administered unless the treating provider makes the

determination that its use is appropriate and required. The provider must give specific written orders to administer the medication(s).

c. If the medication is required and the pharmacy service cannot obtain the medication in a timely manner through the regular or everyday procurement methods, a pharmacist must identify and validate the medication.

d. If authorized for use, the pharmacy service relabels and reissues the medication in accordance with the provider's instructions, using standard labeling as required for inpatient dispensing.

9. MEDICATION ORDERS

a. Electronic order entry using the Computerized Patient Records System (CPRS) must be utilized whenever possible. If unavailable, a legible copy of all prescriber's medication orders must be directly transmitted to the pharmacy. These orders must include all information required by CPRS.

b. All medication orders must be reevaluated by the provider with any change in patient status or relocation to another ward or service. Blanket reinstatement of previous orders for medications discontinued as a result in change of patient status or patient movement is not acceptable. ***NOTE****: In instances when the same treatment team follows the patient after relocation to another ward or unit, local medical center policy may define requirements for stop orders or the reinstatement of prior orders for medications.*

c. To ensure that only medications needed to treat the patient's condition are ordered, a pharmacist must verify all inpatient orders taking into consideration the current diagnosis and the indication for each medication.

d. The medical center must develop a local written policy to establish the required elements of a complete medication order.

e. Since the generic name of a medication is preferred, only the generic name is to be documented in the medication profile. Providers are encouraged to use the generic name whenever possible during the prescribing process. Once the order is verified by the pharmacist, the generic name must be expressed in the patient's medication record.

f. The medical center must develop a written policy that identifies the requirements for indication-for-use on the medication order.

g. Non-formulary medications prescribed for humanitarian or compassionate use must be submitted using the non-formulary request process and receive the Pharmacy and Therapeutics Committee approval prior to use. **NOTE:** *Additional details are available in Directive 2001-044 VA National Formulary Process.*

h. The medical center must develop a written policy that establishes the special precautions or procedures for ordering drugs with look-alike or sound-alike names.

i. Pharmacists are to take appropriate actions, as established by medical center policy, for medication orders that are incomplete, illegible, or unclear.

j. A written policy must be developed that specifies the required elements of any of the following types of orders deemed acceptable for use: As needed, or pro re nata (PRN), or if needed (SOS) orders; standing orders; hold orders; automated stop orders; resume orders (see subpar. 9b); titrating orders; taper orders; range orders; compounded medications; medication-related devices (e.g., nebulizers, catheters, etc.); investigation medications; and medications at discharge.

k. The Pharmacy and Therapeutics Committee must establish a mechanism for reviewing and updating preprinted order sheets, if approved in medical center policy. Preprinted order sheets are only to be considered when prescribing cannot take place utilizing CPRS order entry.

l. A listing of non-approved abbreviations to be avoided during the act of prescribing must be established. This listing must be reviewed by the Pharmacy and Therapeutics Committee and established in local medical center policy.

m. Allergy and adverse drug reaction (ADR) information must be recorded in the electronic medical record. When the electronic medical record is not available and medications are to be administered, documentation must include an allergy or ADR assessment. Medications are only to be dispensed if an allergy assessment has been completed.

n. Pharmacy Service must develop a written facility-approved contingency plan for implementation in the event of computer system failures.

o. Where electronic order entry is unavailable, all medications, including parenteral fluids, must be ordered on VA Form 10-1158, Doctor's Orders, or other approved form. The medication order must have the medication name, dosage, dosage schedule or desired flow rate, duration of therapy, and other information as established by local medical center policy. Automatic stop dates are determined by local medical center policy in accordance with JCAHO standards. ***NOTE:*** *The notation, keep vein open (KVO) or, to keep open (TKO), must be accompanied by the appropriate flow rate determined by the physician.*

p. Verbal or telephone orders are discouraged, however, they may be accepted in an emergency when urgency is a factor and it clearly is in the best interest of the patient. The pharmacist or nurse receiving the verbal or telephone order must immediately commit it to writing and read it back to the provider to verify the accuracy in accordance with local medical center policy. (The verbal order must then be made available electronically according to local VistA recovery plans.)

10. COMPOUNDED STERILE PREPARATIONS

a. Risk levels of all areas must be assessed where sterile products are prepared. All compounded sterile preparations (CSP) must be accurately identified, measured, diluted, and mixed; and be correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed in a manner consistent with USP Chapter <797> provisions (entitled "Pharmaceutical Compounding – Sterile Preparations") and the ASHP Guidelines found at http://www.ashp.org/SterileCpd/797guide.pdf .

b. All hazardous (e.g., cancer chemotherapy) CSPs must be prepared in an appropriate area separate from routine sterile product preparation. Such preparations of potentially hazardous medications must be prepared in a hood that meets all USP, ASHP, and National Institute for Occupational Safety and Health (NIOSH) requirements.

c. Pharmacy personnel are responsible for the preparation and storage of all CSPs, except in emergency circumstances where immediate use is warranted, or when preparation stability is an issue.

d. A pharmacist must check and verify each CSP. The preparation must be discarded if there is any evidence of compounding error, contamination, precipitation, or other physical or chemical incompatibility. If the CSP contains a controlled substance, then a record of the destruction on VA Form 10-2638, Controlled Substance Administration Record, must be completed. This record must have the signatures of two pharmacists who have witnessed the destruction.

e. Manufacturer pre-mixed CSPs that have an outer wrapper must be dispensed for the patient with a label (i.e., double stick, flagged label) that can be affixed to the CSP once the outer wrapper is removed. Local medical center policy must state how pre-mixed CSPs are to be stored, handled, and labeled.

f. The CSP label is to be affixed directly to the preparation and delivered to the patient care area. When a light protective outer bag is required, the label must be affixed directly to the Intraveneneous (IV) product, in addition to the outer bag. These labels must contain the following:

(1) Patient's name;

(2) Identifier number;

(3) Ward and/or medical center locations;

(4) Date prepared;

(5) Identity of each additive, diluents, volume, and flow rate (if specified);

(6) Special instructions (if specified);

(7) Identifier of the preparer and/or checker;

(8) Beyond use date; and

(9) Barcode or the equivalent.

NOTE: *Outer wraps on pre-mixed products must be removed prior to labeling.*

g. All orders and CSPs must be checked by a pharmacist prior to dispensing the product. The following are the minimum requirements for the pharmacist check.

(1) The CSP is checked for accuracy and completeness. Particular attention is to be given to patient identity, identity of the drug additive, amounts added as evidenced by the empty vials or ampoules used, and solutions used. The pharmacist then places their unique identifier on the product label.

(2) Authorized nursing personnel must check the intravenous (IV) label against the physician's order in the virtual due list in Bar Code Medication Administration (BCMA) prior to administering the product to a patient. If there is any discrepancy, the nurse must contact the Pharmacy Service for problem resolution or correction.

h. Unless otherwise specified on the IV label, all unused CSPs must be returned to the pharmacy within 24 hours of receipt.

i. CSPs containing hazardous ingredients must be disposed of according to medical center policy and in accordance with all applicable local, state, and Federal requirements.

11. RADIOPHARMACEUTICALS

a. A radiopharmaceutical is a radioactive compound used for diagnosis and/or therapy of disease. It is a pharmaceutical and, as such, must conform to all legal, ethical, and professional handling requirements of other pharmaceuticals. As it is a radioactive drug, it must conform to all legal and safety requirements established by the Nuclear Regulatory Commission (NRC).

b. Nuclear Medicine Service is responsible for the storage and compounding of radiopharmaceuticals unless a nuclear pharmacist is on staff.

c. Appropriate credentials for all pharmacists involved in the preparation of radiopharmaceuticals are required.

d. Quality control must be in accordance with current Federal Regulations concerning radiopharmaceuticals and radioactive diagnostic agents. Records of all compounded and dispensed material are to be maintained in accordance with current Federal Regulations.

e. Designated areas that conform to Occupational Safety and Health Administration (OSHA) standards are required for the storage, preparation, and disposal of radiopharmaceuticals.

12. BULK COMPOUNDING AND PREPACKAGING

a. Quality control of both the production and the product for bulk compounding must be in accordance with USP Chapter <795>, Professional Standards and Federal Regulations.

b. Appropriate records must be maintained.

(1) A standardized formula or recipe is to be established using VA Form 10 – 2423, Compounding Master Formula card, for the bulk compounded product.

(2) Each manufacturing action of the standardized formula requires the completion of VA Form 10-1361, Pharmacy Manufacturing and Assay Record.

(3) A VA Form 10-1362, Pharmacy Service Prepackaging Record, must be completed to record all unit packaging of a bulk compounded product.

13. PHARMACY STAFFING DURING OFF-HOURS

a. When the onsite pharmacy is not open 24 hours-a-day and 7 days-a-week, a LIP must review the medication order in the pharmacist's absence. This review must be in addition to the prescriber's review, completed before the first dose is administered, and be in accordance with Professional Standards. The pharmacist must conduct a retrospective review of the order as soon as possible, or when the pharmacy opens.

b. Access to medications must be limited to those individuals approved by local medical center policy. Open access to the entire pharmacy by a non-pharmacist is not allowed. Those medications deemed to be emergent can be stored in a night cabinet, automated storage and distribution device, or a controlled section of the pharmacy.

c. A qualified pharmacist must be available either on-call or at another location to answer questions and/or provide access to medications that are not available in the night cabinet, automated storage and distribution device, or the controlled section of the pharmacy.

d. The process for providing after-hours medication must be evaluated on an ongoing basis to determine what medications are accessed routinely and why. Changes must be implemented, as appropriate, to reduce the number of times that non-pharmacist staffs are required to obtain medications from emergency storage.

14. DRUG RECALLS

a. Upon receipt of a written or verbal notification from the Food and Drug Administration (FDA), a pharmaceutical manufacturer, the Facility Recall Coordinator, or other sources, the Chief of Pharmacy Service is responsible for initiating appropriate drug recall procedures.

b. The FDA Recall Guidelines categorizes all recalls into three classes according to the level of potential hazard. Under these guidelines, it is the institution's duty to take full responsibility for product recalls. These duties include follow-up checks to ensure that recall is started,

initiation of progress reports to FDA regarding the recall, and when required, the institution of drug recall from patients. Drug classifications are available at http://www.fda.gov/cdrh/oivd/presentations/041905-bernier_files/textonly/slide16.html

c. If a Class I Recall is announced requiring drug recovery from the patient, a computerized VistA search is to be used to identify all patients who have recently received the recalled drug.

d. The pharmacy's Designated Area Specialist is required to notify the Facility Recall Coordinator to ensure that the VHA Recall Cascade has been initiated.

e. Depending on the nature of the recall, the Chief of Pharmacy Service, or designee, initiates proper documentation for the disposition of the product in accordance with existing Federal Supply Service Regulations. For Class I Recalls, a follow-up report to the Pharmacy Benefits Management Service of all findings and actions may be required.

f. Pharmacy personnel must review all storage areas for the recalled drug including automated dispensing equipment and approved ward stock locations. All recalled drugs must be sequestered so as to prohibit any further use.

g. Pre-packing records must be checked and all applicable lot numbers must be immediately suspended from use.

h. Pharmacy personnel must check all incoming stock to ensure that subsequent receipt of the recalled drug is sequestered.

i. The disposition of all drug recalls must be reported to the Pharmacy and Therapeutics Committee for review and documentation in their meeting minutes.

15. MEDICATION SAFETY

a. It is the responsibility of the Chief, Pharmacy Services, in conjunction with the appropriate Department or Service representatives, to ensure that the medical center identifies drug-related problems and implements measures to improve medication safety.

b. Services or processes that may be utilized to successfully measure or improve medication safety are:

(1) Computerized physician order entry;

(2) Bar Code Medication Administration;

(3) Medication error reporting and multidisciplinary analysis;

(4) Adverse drug event reporting and multidisciplinary analysis;

(5) Utilization of Clinical Pharmacy Specialists to provide:

(a) Pharmacist-based Anticoagulation Clinics;

(b) Pharmacist-based Pharmacotherapy or other specialty clinics;

(c) Multidisciplinary team rounds or meetings;

(d) Concurrent medication review in long-term care facilities;

(e) Pharmacokinetic dosing services;

(f) Antibiotic surveillance services;

(g) Diabetic teaching services;

(h) Pain management services;

(i) Non-formulary and/or restricted drug request review and approval;

(j) Nutritional support services for parenteral nutrition;

(k) Medication use measures; and

(l) Drug information services and newsletters.

c. All necessary actions to reduce the likelihood of intentional or unintentional untoward use of selected point-of-care medications must be taken at each facility. Some of these agents are insulin, potassium, epinephrine, digoxin, lidocaine, pancuronium, succinyl choline, atropine, verapamil and diazepam. Appropriate controls over ward-stocked medications must be included in local medical center policy. This policy must include, at a minimum, the prior-listed agents. These controls ensure the availability of these and similarly stocked agents, provide for patient safety, and facilitate accountability of doses dispensed. Local policy needs to ensure:

(1) Stock levels are limited to necessary quantities, as determined by actual use;

(2) Stock locations are appropriate and necessary, as determined by actual use;

(3) A process of accountable distribution is in place;

(4) Medications are stored in a secure manner;

(5) Access to medication is limited to those persons who dispense or administer medication;

(6) Administration is documented in the permanent patient and hospital or clinic record;

(7) Means to track return and destruction of outdated and unused products (i.e., a return goods contract) is in place; and

(8) A means to reconcile distribution with use exists.

d. The local Pharmacy and Therapeutics Committees must review the issue and consider point-of-care automated dispensing systems to support any manual accountability systems currently in place.

e. The establishment of a multidisciplinary Medication Safety Committee is required for the review of both institutional and national reports of adverse drug events and the development of strategies for improving the safety of the medication use process.

16. HAND HYGIENE

a. Hand hygiene must be a consideration in pharmacy practice and management. Hand hygiene and other hygienic and procedural practices associated with preparing sterile compounded medications are described in the USP, Chapter <797>. Hand hygiene practices for those who provide direct patient care are described in the Centers for Disease Control and Prevention (CDC) Guideline for Hand Hygiene in Healthcare Settings. See Website www.cdc.gov/handhygiene/download/hand_hygiene_core.ppt.

b. For pharmacy staff working to prepare non-sterile preparations and packaging drugs for distribution to inpatients, the following practices are to be observed:

(1) Pharmacy Staff must wash their hands with antimicrobial soap and water (or alcohol based antimicrobial hand rub) in the following situations:

(a) Whenever hands are visibly soiled;

(b) Prior to starting work and prior to returning to work after leaving the pharmacy area;

(c) After all patient contact;

(d) After removal of gloves;

(e) After using the bathroom; and

(f) Before eating. ***NOTE:*** *Eating and drinking must be confined to those areas of the pharmacy where it is not prohibited.*

(2) Pharmacy Staff must decontaminate their hands with antimicrobial soap and water or with an alcohol-based hand rub in the following situations;

(a) After coughing, sneezing, or wiping their nose with a tissue or handkerchief; and

(b) Before donning gloves for any pharmacy work that requires gloving to maintain good hygiene practices.

d. All health care workers who provide direct, hands-on care to patients must not wear artificial fingernails or extenders; this includes non-supervisory and supervisory personnel who regularly or occasionally provide direct, hands-on care to patients. In addition, pharmacy staff preparing sterile products such as medications that will be administered intravenously must not wear artificial fingernails.

e. Management must ensure that disposable gloves, antimicrobial soap, alcohol-based hand rub, and hand lotion designed for use in health care settings are all made available in the work area of pharmacy staff.

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