

INPATIENT PHARMACY SERVICES

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive provides specific direction and procedures related to inpatient clinical activities, inpatient automation, operational efficiencies, and the appropriate storage, handling, and dispensing of medications and supplies for VA medical facility inpatients.
- 2. SUMMARY OF MAJOR CHANGES:** The following are either new or expanded topic areas for this directive: Background, Responsibilities of the Chief of Pharmacy Services, Administration of Medical Management Systems, Automated Pharmacy Systems, Compounded Sterile Products, and Clinical Pharmacy Services.
- 3. RELATED ISSUES:** VHA Directive 2008-080, Recall of Defective Medical Devices and Medical Products, Including Food and Food Products; VHA Directive 2011-001, Providing Bulk Inpatient Medications on Discharge for Outpatient Use, dated January 20, 2011; and VHA Handbook 1108.11, Clinical Pharmacy Services.
- 4. RESPONSIBLE OFFICE:** The Chief Consultant, Pharmacy Benefits Management Services (10P4P), in the Office of Patient Care Services (10P4) is responsible for the contents of this directive. Questions may be addressed to 202-461-6938.
- 5. RESCISSION:** VHA Handbook 1108.06, dated June 27, 2006 and Directive 2011-001, dated January 20, 2011, are rescinded.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of February 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Under Secretary for Health

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INPATIENT PHARMACY SERVICES

1. PURPOSE

This Veterans Health Administration's (VHA) directive provides specific direction, requirements, and procedures related to clinical pharmacy services, pharmacy staff roles, and operational efficiencies as they relate to the integration of automation, and the appropriate storage, handling, and dispensing of all medications and medication related supplies to inpatients. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. The Pharmacy Service must comply with relevant provisions of title 21 of the Code of Federal Regulations (CFR), including Part 1300; relevant standards of The Joint Commission; the practice standards, guidelines, and technical bulletins of the American Society of Health System Pharmacists (ASHP); and the United States Pharmacopeia (USP) National Pharmacy (NP) Chapter 797 (Pharmaceutical Compounding – Sterile Preparations); and Federal privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA), as they pertain to patient privacy.

b. Clinical pharmacists must interact with medical, nursing, and ancillary staff to take an active role in formulating pharmacy related policies and procedures at the VA medical facility. These policies and procedures must incorporate the effective utilization of clinical pharmacist expertise to: perform patient assessment; prospectively evaluate medication therapy; provide medication monitoring; provide comprehensive medication management services; educate patients and other health care providers; and coordinate all dispensing activities for prescribed medications and medical supplies.

c. Clinical pharmacists are allowed, when established under VA medical facility policy, to conduct routine clinical pharmacist duties without the need for an additional authorized Scope of Practice (SOP) (see VHA Handbook 1108.11, Clinical Pharmacy Services). However, consistent with VHA Handbook 1108.11, a clinical pharmacist may also function under an SOP based on their knowledge, skills, abilities, in a specific area of pharmacy practice. When working within an SOP, clinical pharmacists function at the highest level of clinical practice authorized by that SOP to provide comprehensive medication care management for patients in the inpatient setting (see VHA Handbook 1108.11, Clinical Pharmacy Services).

3. POLICY

It is VHA policy that effective medication management and clinical pharmacy systems are utilized for all inpatients in VA medical facilities to ensure the safe delivery of patient-centric care.

4. DEFINITIONS

a. **Automatic Replenishment Drug Distribution System.** The automatic replenishment drug distribution system is a method of drug distribution and inventory management. Under this system, medications are dispensed in the most ready-to-administer forms available from the manufacturer or in unit-doses that have been repackaged by the Pharmacy Service or a licensed repackager, when feasible. This system is not limited to inpatient areas but may be used in unit/ward areas, clinics, and specialty areas of the VA medical facility. Par levels of stock items are established based on the patient care needs in each area.

b. **Batch.** A batch is the preparation of multiple containers of a drug product (e.g., a compounded sterile product) or other pharmaceutical dosage form with uniform character and quality, within specific limits, that are prepared in anticipation of prescription drug orders based on a routine, regularly observed prescribing patterns.

c. **Batch Preparation.** Batch preparation is a single process for the compounding of multiple sterile product units by the same individual, carried out during one limited time.

d. **Beyond-Use-Date.** The beyond-use-date is a date or time after which a compounded sterile preparation (CSP) shall not be stored or transported for its intended use. The date is determined from the date or time at which the preparation is compounded.

e. **Check Analysis of a Pharmaceutical Product.** A check analysis is a second examination of a pharmaceutical drug sample that has been examined and found violative from laboratory analysis. Check analyses are to be conducted by a person other than the original analyst.

f. **Clinical Pharmacist.** A Clinical Pharmacist is the full performance level pharmacist position. All pharmacists are considered clinical pharmacists and for purposes of this directive the term clinical pharmacist is used to encompass all pharmacist positions described in VA Handbook 5005/55, Part II, Appendix G-15 VA Pharmacist Qualification Standards. The role of each clinical pharmacist may differ based on their assignment and must be delineated in their functional statement or scope of practice as appropriate.

g. **Compounding Pharmacy.** A compounding pharmacy is licensed with a State Board of Pharmacy and operating in conformance with applicable Federal laws and State laws regulating its practice. It is managed by licensed pharmacists, engaged in the act of preparing, mixing, assembling, labeling and packaging a drug or device as the result of a practitioner's prescription drug order or initiative. The aforementioned activities are based on the practitioner-patient-pharmacist relationship in the course of professional practice or for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the

preparation of drugs or devices in anticipation of prescription drug orders, on the basis of routine, regularly observed prescribing patterns.

h. **Extemporaneous Compounding.** Extemporaneous compounding is the preparation of a drug product that is not commercially available, upon receipt of a prescription for a specified patient. **NOTE:** *The prescription must be received prior to the shipment of the drug product to the patient.*

i. **Manufacturing (except in the case of bulk compounding, prepackaging or extemporaneous compounding within a pharmacy).** Manufacturing is the production, preparation, propagation, conversion, and processing of a drug or device, either directly or indirectly, through extraction from substances of natural origin or independently through means of chemical or biological synthesis. The term includes any packaging or repackaging of the substance(s) or labeling (or relabeling of its container if repackaged), promotion, and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other authorized health care professionals.

j. **Radiopharmaceutical.** A radiopharmaceutical is a radioactive compound used for diagnosis and/or therapy. It is a pharmaceutical and, as such, must conform to all legal, ethical, and professional handling requirements of other pharmaceuticals.

k. **Unit-Dose Drug Distribution System.** A unit-dose drug distribution system, managed primarily by pharmacy technicians, is a system which permits identification of the drug up to the point of administration and is the primary distribution system for all inpatient areas. Medications dispensed are 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 Programs).

5. RESPONSIBILITIES OF THE VA MEDICAL FACILITY CHIEF, PHARMACY SERVICE

The Chief of Pharmacy Service is responsible for ensuring that:

a. A medication management system that is safe and effective is implemented (see paragraph 6 of this directive).

b. All Veterans Health Information Systems and Technology Architecture (VistA) pharmacy applications, developed for information management, are appropriately utilized.

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

d. Adequate staffing and space, as defined by existing criteria (VA Facility Design Guides from the Office of Construction & Facilities Management_ <http://www.cfm.va.gov/til/dGuide.asp>), is provided for inpatient medication distribution, administrative and clinical programs.

e. Workspaces where medications are handled are clean, orderly, well-lit, and free of clutter, distraction, and noise.

f. A process is in place to document the initial orientation, competency assessment, and annual competencies of all pharmacy professional, technical, and ancillary support staff.

g. All confidential documents are handled in compliance with VA policy and applicable laws and regulations, including HIPAA guidelines.

h. Pharmacy Service provides direction regarding the receipt, distribution, control, accountability, and quality of medications used throughout the VA medical facility.

i. An annual assessment is conducted of the processes used throughout the VA medical facility for CSP, consistent with established standards and best practices (see paragraph 10 of this directive).

j. Pharmacy services supports the Radiation Safety Officer in the development of local VA medical facility policy and training associated with radiopharmaceutical receipt, storage, security, compounding, delivery, and waste disposal.

k. The VA medical facility identifies medication-related problems and implements measures to improve medication safety; in conjunction with the appropriate Department or Service representatives.

l. Clinical Pharmacy services that support medication safety and comprehensive medication management services for inpatients are developed and available for review in VHA Handbook 1108.11.

m. The remaining portions of partially-used bulk inpatient medications (e.g., inhalers, eye drops, creams, etc) are provided to patients with the required outpatient labeling, when appropriate, upon discharge (see subparagraph 9.q.).

n. Patient counseling, individualized patient education, or written patient information is provided to patients at discharge from the VA medical facility as required by law, regulation, accrediting agencies, or VA policy.

o. Automated systems meet the requirements stated in paragraph 7.

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 clinical pharmacist prior to the administration of the drug, except when required for emergent need or where all processes are controlled by a licensed independent practitioner (LIP). In those instances where a prior review is not possible, the clinical pharmacist must review the order as soon as possible, within 24 hours, in accordance with The Joint Commission requirements.
- b. Orders are dispensed for individual patients up to a 24-hour period. In the case of nursing home care units (NHCU), long-term care units, Residential Rehabilitation Treatment Programs or domiciliary units, quantities in excess of a 24-hour supply may be issued (e.g., 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 drug distribution systems. Pharmacy technicians are authorized to restock unit dose medications to automated dispensing units and medication carts without requiring a second check (by other pharmacy personnel) with the existence of adequate quality assurance and controls (i.e., Bar Code Medication Administration [BCMA], bar-code capable automation, nurse verification on input, etc). The quality assurance and control aspects of the unit-dose drug distribution must be delineated in VA medical facility policy and job specific competencies related to unit dose dispensing must be part of the technician's performance plan and review.
- c. Standardized administration times and response times for first doses are established in VA medical facility policy to ensure the timely administration of medications, including off-schedule dispensing of "STAT," "NOW," and change orders.
- 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 (e.g., Pyxis, Omnicell, AcuDose, etc.) are used, a software interface with VistA is required for inpatient areas. **NOTE:** *Patient profiling interfaces should be enabled in other areas if technology permits.*
- e. If VA medical facility 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. **NOTE:** *For handling of approved drug samples and drug-related supplies in accordance with VA policy, see VHA Handbook 1108.10, Promotion of Drugs and Drug-Related Supplies by Pharmaceutical Company Representatives.*
- 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 for those products available as 'ward stock' and provided to the unit or clinic independent of a patient-specific order. Pharmacy personnel maintain and utilize these computer records for inventory accountability.
- g. Stock levels, consistent with the patient care needs of the using unit or clinic, are established by pharmacy and unit or clinic manager.

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

i. Appropriate prepackaging records, such as the VA Form 10-1362, Pharmacy Service Prepackaging Record (see Appendix A), or the electronic equivalent, is maintained to ensure complete identification in the case of a drug recall or other need for validation. **NOTE:** *These records are to be retained for a period of 3 years.*

j. The monitoring of medication refrigerator temperature is in accordance with local medical center policy, which is to be based on The Joint Commission standards and USP requirements. **NOTE:** *Only pharmaceutical items are permitted in medication storage refrigerators.*

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 refrigeration 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 and the appropriate clinical pharmacist oversight. Records of all monthly inspections are to be maintained for future review and trending. It is recommended that pharmacy technicians have responsibility for the storage area review aspect of this activity. **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 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. Automated pharmacy systems must include a standardized Health Level 7 (HL7) interface to the VistA system.

d. The Chief of Pharmacy Services, or designee, must:

(1) Establish local medical center 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 to be 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.

(2) Establish performance requirements for the manufacturer during installation and the automated pharmacy system after implementation. The requirements are to include workflow assessment, installation, staff training and equipment maintenance.

(3) Develop a plan for ensuring the safe and efficacious use of the system(s) with a focus on patient safety. The plan needs to identify the minimum standards for routine assessment through an established monitoring and quality assurance program. The plan needs to address high-risk and hazardous drugs, look-alike sound-alike medications, and any potential for medication errors and controlled substance discrepancies. The plan must be established to address the removal, security, re-stock to pharmacy inventory, and accountability of medications when a system is removed from a patient care area.

(4) Establish a contingency plan in the event of a power, system or process failure; including who is to be notified and how the system's medications are to be secured and processed. **NOTE:** *It is recommended that a routine be established to determine: if a system failure is imminent, how to identify when a system failure occurs, how to compensate in order to protect patient safety when failures occur, and how failures are to be corrected expeditiously.*

(5) Ensure that patient confidentiality is maintained in accordance with HIPAA standards (see Health Information Privacy at: <http://www.hhs.gov/ocr/privacy/index.html>). Safeguards must be established to prevent "outside" access to patient data.

(6) Assign all activities associated with equipment assessment, routine maintenance, and oversight to appropriately trained and credentialed pharmacy technicians when possible. Job-specific competencies, related to the care and operation of the automated pharmacy system(s), must be part of the pharmacy technician's performance plan and review.

(7) Implement an ongoing quality assurance program that monitors performance of the automated pharmacy system. Standards and required documentation must be included in local medical center policy.

8. MEDICATION BROUGHT INTO A VA MEDICAL CENTER BY PATIENTS

a. In those instances when the pharmacy service cannot obtain a medication or supply in a timely manner through the regular or everyday procurement methods, a pharmacist can authorize the use of a patient's own medication when ordered by the provider.

b. A process must be established to safely control (i.e., approve for use), or manage, outpatient medications/supplies (e.g., VA or non-VA dispensed) brought into the VA medical facility by the patient or family member. VA medical facility policy must provide guidance as to the use, disposition, storage, or return of these medications/supplies that is consistent with this directive.

c. For those VA medical facilities that allow patients to bring outpatient medications/supplies into the medical center, these products must not be administered unless the treating provider makes the determination that their use is appropriate and required. The provider must enter specific orders into the patient's medical record authorizing the use or administration.

d. When the required approvals have been processed and the medication/supply is deemed necessary, a clinical pharmacist must identify and validate the correctness of the medication prior to dispensing or administration to the patient.

e. When an outpatient medication is authorized for inpatient use, the Pharmacy Service must relabel the medication in accordance with the provider's instructions. This must be done using standard labeling as required for inpatient dispensing, prior to reissue.

9. MEDICATION ORDERS

a. VA authorized providers must utilize the Computerized Patient Record System (CPRS) for electronic order entry whenever possible. If unavailable, a legible copy of all prescriber medication orders must be directly transmitted to the pharmacy. These orders must include all information required by CPRS.

b. VA medical facility policy must specify the required elements of any of the following types of inpatient orders that are deemed acceptable for use: as needed, or pro-re-nata (PRN), orders; if needed (SOS) orders; standing orders; hold orders; automated stop orders; resume orders; titrating orders; taper orders; range orders; compounded medication orders; medication-related device orders (e.g., nebulizers, catheters, etc.); investigational medication orders; transfer and discharge medications orders.

c. All medication orders must be reevaluated by the provider with any change in patient status or relocation to another ward or service. **NOTE:** *In instances when the same treatment team follows the patient after relocation to another ward or unit, VA medical facility policy may define requirements for stop orders or the reinstatement of prior orders for medications.*

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

e. The generic drug name is the preferred nomenclature for medication prescribing and labeling. Providers are encouraged to use the generic name whenever possible during the prescribing process. Once the order is verified by the clinical pharmacist, the generic name must be expressed in the patient's medication record.

f. Each VA medical facility must define, in local policy, the requirements for indication-for-use on the medication order.

g. Provider requests for the approval of non-formulary medications prescribed for humanitarian or compassionate use (e.g., an investigational new drug) are to be submitted using the non-formulary request process and must receive approval by the Pharmacy and Therapeutics Committee (P&T) prior to use. **NOTE:** *Additional details are available in VHA Handbooks 1108.04 and 1108.08.*

h. Look-alike or sound-alike drug names require special precautions and therefore, VA medical facility policy must communicate procedures for ordering, storage, prescribing and administering these medications (see paragraph 15.a.(3)).

i. Clinical pharmacists are to take appropriate actions, as established by VA medical facility policy, for medication orders that are incomplete, illegible, or unclear.

j. The P&T must establish a mechanism for the review of medication order sets in accordance with local medical center policy. These order sets may be established within CPRS using the OE/RR order set functionality, progress note templating functionality (TIU Templates and/or Clinical Reminder Dialogs), or using an external software application that interfaces with CPRS Orders. Preprinted order sheets (i.e., paper) are only to be considered when prescribing cannot take place utilizing one of the electronic order entry pathways described earlier in this paragraph.

k. A listing of non-approved abbreviations, to be avoided during the act of prescribing, must be established in local VA medical facility policy and reviewed by the P&T. The Joint Commission Official "Do Not Use" List is found at https://www.hnfs.com/content/dam/hnfs/tn/prov/news/pdf/Prov_News_10_2010_V6_I10.pdf.

l. Allergy and adverse drug reaction (ADR) information must be recorded in CPRS. When the CPRS is not available and medications are to be administered, documentation must include an allergy assessment. Medications are only to be dispensed if an allergy assessment has been completed. **NOTE:** *In emergent situations, when no allergy assessment can be made, the patient's provider can exercise authority to override this practice on an order by order basis.*

m. When CPRS is not available, a facility-approved contingency plan for implementation (e.g., VistA Read-Only), in support of item 9.l., must exist in local VA medical center policy in the event of a computer system failure.

n. When electronic order entry is unavailable, all medications, including parenteral fluids, must be ordered on VA Form 10-1158, "Doctor's Orders," or another locally 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 VA medical center policy.

NOTE: *The notation, keep vein open (KVO) or, to keep open (TKO), must be accompanied by the appropriate flow rate, as determined by the covering provider.*

o. Automatic stop dates for medications are to be established and published in VA medical facility policy in accordance with The Joint Commission standards.

p. Verbal or telephone medication orders are discouraged, but may be accepted in an emergency when urgency is a factor and it clearly is in the best interest of the patient. The clinical 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 VA medical facility policy. **NOTE:** *The verbal order must then be recorded electronically according to local VistA use policies.*

q. Upon discharge, the remaining portions of partially-used bulk medications (e.g., inhalers, eye drops, creams or ointments) identified to specific patients, will be relabeled to meet outpatient prescription requirements and dispensed to those patients, when appropriate. **NOTE:** *The relabeling of these products is to be in compliance with all applicable laws and regulations. VA medical facilities that do not have inpatient beds are exempt.*

r. Before administering a new medication, the patient or patient's representative is to be informed about any potential for clinically significant adverse drug reactions or other concerns regarding administration of a new medication. Authorized medical facility personnel (e.g., providers, nurses, etc) must support this communication effort in the absence of the clinical pharmacist.

s. Locally established "Telehealth Service Agreements" (e.g., Tele-ICU) must identify in local medical facility policy the procedure for contacting the telehealth provider when medication order clarification is required.

10. COMPOUNDED STERILE PREPARATIONS

a. VA medical facilities must ensure that all compounded sterile preparations (CSP) are prepared and stored in accordance with standards that are in compliance with: United States Pharmacopeia Chapter 797 (USP <797>) "Pharmaceutical Compounding – Sterile Preparations", United States Pharmacopeia Chapter 800 (USP <800>) "Hazardous Drugs – Handling in Healthcare Settings", applicable USP compendial standards described in the USP General Chapters; and Guidelines for Safe Preparation of Sterile Compounding (2013) published by the Institute for Safe Medication Practices (ISMP). The risk level in all areas of preparation must be assessed where sterile products are prepared. All CSPs must be accurately identified, measured, diluted, and mixed. They must also be correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed in accordance with:

- (1) USP <797> provisions;
- (2) USP <800> provisions
- (3) VHA PBM Guidance for CSPs;
- (4) The CSP Guidance Flowchart Diagram; and

(5) The VHA PBM Assessment Guide for CSPs, within VA medical facilities and outsourced compounding pharmacies (see [VHA PBM CSP GUIDANCE DOCUMENTS - All Documents](#)). **NOTE:** *Compliance with these standards is a requirement of all VA pharmacies whether they are prepared for in-house use or for outsourcing. This is an internal link and is not accessible to the public.*

b. VA medical facilities are required to use commercially available sterile admixtures and drug products or, when unavailable, commercially available alternative drug products. If commercially prepared products are unavailable, VA medical facility pharmacies shall compound sterile drug products as needed in accordance with the standards cited in paragraph 10.a. above. The compounding of all “high risk level” CSPs (in accordance with USP <797> and USP <800> standards) by a VA medical facility pharmacy, requires the Pharmacy Service to be accredited by the Pharmacy Compounding Accreditation Board (PCAB) or an equivalent accrediting body. If the VA medical facility pharmacy determines it is necessary to outsource CSPs from an external compounding pharmacy establishment, the decision to do so is governed by the “VHA PBM Guidance for the Preparation of Compounded Sterile Pharmaceutical Products.”

c. 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 USP <797> and USP <800> compliant primary and secondary engineering control systems or devices that meet all USP, ASHP, and National Institute for Occupational Safety and Health (NIOSH) requirements. All hazardous drug products shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure that conform with USP <800> requirements.

d. 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.

e. Pharmacy personnel must affix the CSP label 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 intravenous (IV) product, in addition to the outer bag. These labels must contain the following:

- (1) The patient's name;
- (2) An identifier number;
- (3) Ward and/or medical center location;
- (4) The date prepared;
- (5) Identity and strength of each additive and diluent(s);
- (6) The volume, flow rate (if specified) and route of administration;

- (7) Special instructions (if specified);
- (8) Appropriate auxiliary labeling (including precautions) attached;
- (9) The beyond-use-date (BUD);
- (10) Storage requirements;
- (11) A barcode or the equivalent; and

(12) Identification of pharmacy personnel that prepared and checked the CSP, one of which must be a pharmacist. **NOTE:** *A check of the final product is required except in cases where only one person is staffing (e.g., on the off-tour, when only a pharmacist is staffing).*

f. End product evaluation and visual testing for all CSPs prepared in-house and any CSP procured from an outsourced vendor, for use in-house, must be checked by a clinical pharmacist prior to dispensing the product for patient administration. The end product testing shall include an evaluation for:

- (1) Container leaks;
- (2) Container integrity;
- (3) Solution cloudiness or phase separation;
- (4) Particulates in the solution;
- (5) Appropriate solution color;
- (6) Solution volume; and

(7) Identity of the drug and additives (e.g., drugs, diluents, solutions) with the quantity of each additive evidenced by the empty vials or ampoules used. **NOTE:** *This item pertains to those products compounded in-house.*

g. Unless otherwise specified on the IV label, all unused CSPs must be returned to the pharmacy when discontinued or the following morning if not administered. CSPs may be re-cycled for use provided their BUD has not been exceeded and their storage requirements have been maintained. End-product evaluation shall be conducted for all re-cycled CSPs as denoted in paragraph 11.f.

h. CSPs containing hazardous ingredients must be disposed of in accordance with local VA medical facility policy, and all applicable local, State, and federal requirements.

11. RADIOPHARMACEUTICALS

a. A radiopharmaceutical 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 clinical pharmacist is on staff.

c. The appropriate credentials are required for any clinical pharmacists involved in the preparation of radiopharmaceuticals. Examples are; Certification by the Board of Pharmaceutical Specialties or substantial practice time devoted to the practice of nuclear medicine.

d. Quality control must be in accordance with current Federal Regulations (e.g., 42 CFR 482, 10 CFR 35) concerning radiopharmaceuticals and radioactive diagnostic agents. Records of all compounded and dispensed material are to be maintained in accordance with the VA Records Control Schedule RCS 10-1, Section XV.

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> and Professional Standards.

b. Appropriate records must be maintained, to include the following:

(1) A standardized formula or recipe is to be established using VA Form 10 – 2423, Compounding Master Formula card (see Appendix B), 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. A final check of the product and VA Form 10-1362 must be performed by a pharmacist and the Prepackaging Record signed by that individual confirming the review.

13. PHARMACY STAFFING DURING OFF-HOURS

a. When the onsite pharmacy is not open 24 hours-a-day and 7 days-a-week, a contingency plan must exist to assure a review of the medication order prior to administration. This review of the medication orders may be performed by a clinical pharmacist at a remote location, or an LIP in emergent situations. This review must be performed by an individual who is not the prescriber and completed before the first dose is administered. When an order is reviewed by an LIP, a clinical pharmacist must conduct a retrospective review of the order as soon as possible, or when the pharmacy opens, whichever is sooner.

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

c. A qualified clinical 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 access section of the pharmacy in emergent situations, as stated in local VA medical center policy.

d. The process for providing after-hours medication must be evaluated on an ongoing basis, in accordance with VA medical facility policy, to determine what medications are routinely accessed and why. Changes must be implemented, as appropriate, to reduce the number of times that non-clinical 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 VA National Center for Patient Safety, the VA medical facility Recall Coordinator, or other source, the Chief of Pharmacy Service is responsible for initiating appropriate drug recall procedures.

b. The FDA Recall Guidelines (see FDA Investigations Operations Manual 2014, Chapter 7, page 356) categorize recalls into three classes according to the level of potential hazard. Under these guidelines, it is the facility'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 at what point the institution of drug recall from identified patients is required. It is recommended that pharmacy technicians assume primary responsibility for management of drug recalls with appropriate clinical pharmacist oversight.

c. If a "Class I Recall" is announced, requiring drug recovery from the patient, the Chief of Pharmacy Services, or designee, must make sure the following takes place:

(1) Authorized VA medical facility staff must initiate a computerized VistA search to identify all patients who have recently received the recalled drug.

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

(3) 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. **NOTE:** *For all Class I Recalls, a follow-up report to the Pharmacy Benefits Management Service of all findings and actions may be required.*

(4) Pharmacy personnel must review all storage areas for the recalled drug including automated dispensing equipment and approved ward stock locations.

(5) All recalled drugs must be sequestered by pharmacy service so as to prohibit any further use.

(6) Pre-packing records must be checked for inclusion of the recalled product and all applicable lot numbers must be immediately suspended from use by Pharmacy Service.

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

(8) The disposition of all drug recalls must be reported to the P&T for review and documentation in their meeting minutes by Pharmacy Service.

NOTE: *Each VA medical facility will define in local policy the procedure for responding to Class II and III.*

15. MEDICATION SAFETY

Pharmacy Service, in conjunction with the appropriate Department or Service representatives, will ensure that:

a. The VA medical facility identifies medication-related problems and implements measures to improve medication safety. Examples may include:

(1) Computerized physician order entry.

(2) BCMA.

(3) Medication error reporting and multidisciplinary analysis.

(4) Adverse drug event reporting and multidisciplinary analysis.

(5) The provision of clinical pharmacy services (see VHA Handbook 1108.11).

(6) The appropriate use of anticoagulation therapy.

(7) Documentation of medication administration in the permanent patient and hospital or clinic record.

(8) Tracking of returns and the destruction of outdated and unused products (e.g., a Return Goods Contract).

(9) Reconciliation of medication distribution with usage.

b. 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. Point of care medications may be located in hospitals, community living centers, domiciliary,

outpatient surgical and procedure clinics. Some of these agents are insulin, ophthalmic medication drops, 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, provided 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 for responsible distribution is in place.
- (4) Medications are stored in a secure manner.
- (5) Access to medication is limited to authorized personnel who dispense or administer medication.
- (6) Administration is documented in the permanent patient and hospital or clinic record.
- (7) A means to track the return and destruction of outdated and unused medications (e.g., a Return Goods Contract) is in place.
- (8) A means to reconcile distribution with use exists.
- (9) Use of multi-dose products stored in ward stock centralized areas and outpatient surgical and procedure clinics must be labeled with an expiration date upon opening or entering the multi-dose product (e.g., to include but not limited to parenterals, insulin, ophthalmic drops) that does not exceed 28 days; or a shorter expiration date when recommended by the manufacturer.

NOTE: For a listing of high-alert medications, see <http://www.ismp.org>. For a list of hazardous medications, see <http://www.cdc.gov/niosh/docs/2004-165/>.

c. The VA medical facility identifies a list of look-alike/sound-alike medications it stores or dispenses, as required in The Joint Commission standards. The VA medical facility must take action to prevent errors involving the interchange of the medications on its list of look-alike/sound-alike medications. In addition, this list must be reviewed annually and revised as necessary. **NOTE:** A source for look-alike/sound-alike medications can be found on The Institute for Safe Medication Practices website (<http://www.ismp.org/Tools/confuseddrugnames.pdf>).

d. The local P&T reviews medication safety issues and considers point-of-care automated dispensing systems to support any manual accountability systems currently in place.

e. A multidisciplinary committee is required for the review of both institutional and national reports of adverse drug events, medication errors, and near misses. This committee must also address the development of strategies for improving the safety of the medication use process. A written process must exist that describes how the VA medical facility responds to, implements, and complies with external reporting requirements for: potential or actual adverse drug events; significant adverse drug reactions; and medication errors.

16. CLINICAL PHARMACY SERVICES

a. Clinical pharmacy services are integral to VHA's comprehensive health care initiatives. Patient care is improved by maximizing the comprehensive medication management capabilities of the pharmacist and fully integrating clinical pharmacy services into all team-based models. The Chief of Pharmacy Services will identify the best use of pharmacy staff and resources through process improvement activities, emphasizing evolving pharmacist and technician roles. This includes: the use of automation; identification of key roles for pharmacy technicians; opportunities to expand medical facility policy with safe medication practices; augmentation of the assignment of clinical pharmacists to patient care activities (outlined in VHA Handbook 1108.11, Clinical Pharmacy Services).

b. Clinical pharmacists practice in a wide variety of settings including inpatient, ambulatory care, community and home based care, and specialty care; providing comprehensive medication management services to Veterans. Their patient care activities are described in VHA Handbook 1108.11, and are included in the role of all pharmacist positions, as appropriate. Clinical pharmacists, in accordance with local and VISN policy, Federal laws and regulations, and SOPs when required, conduct inpatient medication activities including, but not limited to:

- (1) Medication profile reviews and reconciliation;
- (2) Medication counseling;
- (3) Prescription processing;
- (4) Dispensing bridge supplies of maintenance medications;
- (5) Anticoagulation management;
- (6) Pharmacokinetic dosing services and management;
- (7) Management of nutritional support;
- (8) Pain management services;
- (9) Antimicrobial stewardship activities;
- (10) Medication monitoring;

(11) Non-formulary drug reviews;

(12) Formulary management; and

(13) The identification, resolution, and follow-up on medication-related problems identified throughout the medication management process.

NOTE: *They also provide the required oversight of technical staff in all aspects of medication distribution.*

c. Pharmacy technicians play an integral role in the dispensing and administrative processes that are essential to pharmacy operations. The proper selection, training, competency assessment, and deployment of pharmacy technical staff is crucial to clinical pharmacy activities as Clinical Pharmacists move away from routine medication and product dispensing and into direct patient care clinical activities. VA pharmacy leaders should ensure that technicians are fully utilized in these roles as appropriate. Pharmacy technician duties may include those described in this directive and the following:

(1) Managing controlled substances by filling, recording, and justifying the remaining quantity of CS for accuracy with regard to inpatient nursing requests for ward stock replenishment of controlled substances;

(2) Managing automation through maintenance, cleaning, proper operation, replenishing the drug supplies, etc;

(3) Conducting ward inspections;

(4) Prescription fulfillment;

(5) Compounded sterile preparations;

(6) Unit-dose dispensing or performing a second check (e.g., technician-check-technician);

(7) Quality assurance and medication-use-evaluation data collection; and

(8) Managing drug and supply inventories by inventorying, ordering, receiving, justifying invoices, replenishing shelves with inventory, removing outdated inventory, etc.

17. 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 CSP 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

www.cdc.gov/handhygiene and the following Web site
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 the approved areas of the pharmacy.*

(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.

c. 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 CSP must not wear artificial fingernails.

d. Pharmacy 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 for pharmacy staff.

18. REFERENCES

a. American Society of Health-System Pharmacists. ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices. American Journal of Health System Pharmacists (AM J Health-Syst Pharm) 1998 July; 55(13):1403-1407.

- b. American Society of Health-System Pharmacists. ASHP Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures. AM J Health-Syst Pharm. 2000 July; 57(14):1343-1348.
- c. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role with respect to drug delivery systems and administration devices. American Journal of Hospital Pharmacists (AM J Hosp Pharm) 1993; 50:1724-5.
- d. American Society of Hospital Pharmacists (ASHP) Discussion Guide on USP Chapter <797> for Compounding Sterile Preparations.
- e. American Society of Hospital Pharmacists, ASHP Guidelines on Outsourcing Sterile Compounding Services.
(<http://www.ashp.org/DocLibrary/BestPractices/MgmtGdlOutsourcingSterileComp.aspx>).
- f. American Society of Hospital Pharmacists (ASHP) Outsourcing Sterile Products Preparation, Contractors Assessment Tool.
- g. American Society of Hospital Pharmacists (ASHP) Technical Assistance Bulletin on Pharmacy-Prepared Ophthalmic Products, Am J Hosp Pharm. 1993;50:1462-3.
- h. Antimicrobial Effectiveness Testing (General Information Chapters <51>). In: The United States Pharmacopoeia, 36th rev., and the National Formulary, 31st ed. Rockville, MD: United States Pharmacopoeia Convention; 2013.
- i. Bakri, S., Snyder, M., Pulido, J., McCannel, C., Weiss, W., Singh, R.; Six-Month Stability of Bevacizumab (Avastin) Binding to Vascular Endothelial Growth Factor after Withdrawal into a Syringe and Refrigeration or Freezing. Retina: 2006 May-Jun; 26(5):519-22.
- j. Barker KN. Ensuring Safety in the Use of Automated Medication Dispensing Systems. Am J Health-Syst Pharm. 1995;52:2445-7.
- k. Gonzalez, S., Rosenfeld, P., Stewart, M., Brown, J., Murphy, S.; Avastin Doesn't Blind People, People Blind People; Compounding Avastin For Intravitreal Injection; American Journal of Ophthalmology, 2012 Feb;153(2):196-203.
- l. Gray, J., Stark, A., Berchtold, M., Mercier, M., Neuhaus, G., Worth, A.; Introduction of a Rapid Microbiological Method as an Alternative to the Pharmacopoeial Method for the Sterility Test. American Pharmaceutical Review. 2010 October.
- m. Guidelines for Intravitreal Injections established by the Surgical Advisory Boards (SAB), http://vaww.dushom.va.gov/DUSHOM/surgery/specialty_surgical_programs.asp.
NOTE: This is an internal VA Web site and is not available to the public.
- n. 45 CFR Parts 160, 162, and 164.

- o. Institute for Safe Medication Practices (ISMP), Medication Safety Alert (Acute Care): Safe Practices in Pharmacy Sterile Compounding Areas; June 2, 2011; Volume 16, Issue 11.
- p. Institute for Safe Medication Practices (ISMP), Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013.
- q. Kastango, ES. Quality-Control Analytical Methods: USP <797> Compounded Sterile Preparations; Sterility Requirements and their Relationship to Beyond-Use Dating. International Journal of Pharmaceutical Compounding, 2004 Sept-Oct;8(5):393-397.
- r. Off Label Use of bevacizumab (Avastin®) for intravitreal injection, VHA Pharmacy Benefits Management Strategic Healthcare Group, the Medical Advisory Panel, and the Office of the Chief Consultant for Ophthalmology, updated November 2010
<http://www.pbm.va.gov/vacenterformedicationsafety/nationalpbmbulletin/NationalPBMBulletinBevacizumab.pdf>
- s. Parveen, S., Kaur, S., Kenney, J., McCormick, W., Gupta, R; Identifying Faster Sterility Tests for Biological Products; Center for Biologics Evaluation and Research (FDA).
- t. Pharmaceutical Compounding: Non-sterile Preparations, (General Information Chapter <795>). In: The United States Pharmacopoeia, 28th rev., and the National Formulary, 23rd ed. Rockville, MD: United States Pharmacopoeia Convention; 2005:2457-2460.
- u. Pharmaceutical Compounding - Sterile Preparations, (General Information Chapter <797>). In: The United States Pharmacopoeia, 36th rev., and the National Formulary, 31st ed. Rockville, MD: United States Pharmacopoeia Convention; 2013.
- v. Hazardous Drugs – Handling in Healthcare Settings (General Information Chapter <800>). In: The United States Pharmacopoeia, 39th rev., and the National Formulary, 34th ed. Rockville, MD: United States Pharmacopoeia Convention, 2016.
- w. Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for Safe Preparation of Sterile Compounds 2013
<http://www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf>
- x. Sanborn, M. Outsourcing Compounding Services to meet USP Chapter <797> Requirements: An Overview; *Pharmacy Practice News*, 2008; 35(9).
- y. Subramaniam V, Coggins P, Dang C, Vargas J. USP 797 Monitoring Guidelines: Standards for Pharmacy Practice; *Pharmacy Practice News*, 2011:38(4).

z. Title 38 United States Code (U.S.C.) Part V, Chapter 73, Subchapter 3, Section 7332, “Confidentiality of Certain Medical Records.”

aa. The United States Pharmacopeia Convention (USPC), Chapter 71: Sterility Tests. United States Pharmacopeia; Copyright 2008.

bb. The United States Pharmacopeia Convention (USPC). Chapter 797: Pharmaceutical compounding—sterile preparations. In: *The United States Pharmacopeia*, 30th ed., and the *National Formulary*, 25th ed. Rockville, MD: USPC; 2007.

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