PHARMACY GENERAL REQUIREMENTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides specific policy, procedures, and responsibilities for the management of the Department of Veterans Affairs (VA) Pharmacy Services on varied topics that require standardization in VA medical facilities.

2. SUMMARY OF MAJOR CHANGES:

a. Amendment dated, January 26, 2021, incorporates current policy information from VHA Directive 1087, Monitoring of Expired or Soon-to-Expire Medication Returns, dated August 21, 2019 (see paragraph 5.b., responsibilities associated VA medical facility Chief of Pharmacy).

b. As published on March 10, 2017, this policy included the requirement to submit certain prescription data to states which allow VA to enroll in their Prescription Drug Monitoring Programs (PDMP), statements on pharmacy procurement and contracting activities, and requirements for the provision of medication in home health care settings.

3. RELATED ISSUES: VHA Handbooks 1108.01, 1108.02, 1108.03, 1108.04, 1108.05, and 1108.06.

4. RESPONSIBLE OFFICE: The Office of Patient Care Services, Pharmacy Benefits Management Services (12PBM)), is responsible for the contents of this directive. Questions may be addressed to the Chief Consultant at 202-461-7360.

5. RESCISSIONS: VHA Handbook 1108.07, dated April 17, 2008; VHA Manual M-6, Part II, Chapter 5, Pharmacy Service; and VHA Manual M-1, Operations. Part IX, Chapter 21, Paragraphs 21.01 through 21.07 and Appendices 21A and 21B, Staffing Guidelines and Productivity Enhancements, Pharmacy Services, are rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

/s/ Poonam Alaigh, M.D.
Acting Under Secretary for Health

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PHARMACY GENERAL REQUIREMENTS

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy, procedures, and responsibilities for the management of the Department of Veterans Affairs (VA) Pharmacy Services. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301, 7305 and 7401; 38 CFR 1.483, 1.515 and 17.38.

2. BACKGROUND

a. VHA Pharmacy Services are essential components of VA's health care system. The safe, appropriate, and cost-effective use of medications is the overarching goal of VA pharmacy programs. VA is a recognized leader in the specialty of professional pharmacy practice and post-graduate pharmacist education. External organizations and pharmacy programs nationwide consider VA pharmacy practice to be the professional benchmark in many areas of care. This directive is intended to identify the basic institutional support requirements for VA Pharmacy Services to ensure both consistency of care throughout VA and the continued advancement of VA pharmacy as an industry leader.

b. The Pharmacy Benefits Management (PBM) Service, as an essential component of the health care delivery team in VA, is charged with the coordination and provision of patient oriented pharmaceutical services.

(1) The services provided have evolved from core procurement and distributive functions to include: formulary management and pharmaceutical supply chain integrity; drug safety through pharmacovigilance, Comprehensive Medication Management (CMM) and risk reduction; adverse drug event reporting; drug cost avoidance and contract compliance; Consolidated Mail Outpatient Pharmacy (CMOP); Emergency Pharmacy Services (EPS); Federal pharmacy collaboration; and complex clinically based activities.

(2) The clinical pharmacy activities involve maximizing the CMM capabilities of the Clinical Pharmacist and fully integrating clinical pharmacy services into team-based models of care. This includes the ability to perform physical assessments; hold prescriptive authority; order, interpret, and monitor laboratory results; and develop patient-centered therapeutic plans, such as:

(a) Identifying operational efficiencies that can deliver maximum benefit to the patient and guarantee safety, proper medication use, and the delivery of clinical care that closes gaps in any unmet patient need (see Appendix A).

(b) The provision of medications in a home health setting.

3. DEFINITIONS

a. **Chief of Pharmacy.** The Chief of Pharmacy is the VA employee who has primary responsibility for the provision of professional and distributive pharmacy services within a VA medical facility. Qualifications for the Chief of Pharmacy include an active and unrestricted license to practice pharmacy which must be issued by a state, territory of the United States, or the District of Columbia. This individual is sometimes referred to by other titles in the private sector, including Pharmacy Site Manager, Pharmacist Director, etc.

b. **Collaborative Medication Management.** Collaborative medication management entails agreements between physicians, or other LIPs, and pharmacists. Under the agreement's scope pharmacists may perform all facets of comprehensive medication management which includes: initiating, modifying, and continuing medication regimens; ordering related laboratory tests and diagnostic studies; performing physical measurements and objective assessments; taking independent corrective action for identified drug-induced dilemmas; and ordering consults (e.g., dietician, social work, specialty provider) as appropriate, to maximize positive drug therapy outcomes as defined in their scope of practice.

c. **Comprehensive Medication Management (CMM).** CMM is the standard of care that ensures each patient's medications (VA dispensed, non-VA dispensed, herbal, alternative, and over-the-counter medications) are individualized and optimized for the specific patient. This optimization is based on the patient's medical condition(s), comorbidities, individualized patient parameters (e.g., age-related changes in pharmacokinetics, the pharmacodynamics of medications, etc.), and patient-centered care factors. CMM includes the management of chronic diseases, the acute manifestations of these processes, and management of adverse reactions or events to medications. It includes components of medication therapy management but is a broader term that encompasses a larger spectrum of services that are provided by pharmacists. In addition, CMM takes into account: drug-food, drug-drug, and drug-disease interactions and includes a patient-specific therapeutic plan, goals, and monitoring to ensure the best possible outcome. Finally, as a part of CMM, the patient understands, agrees with, and is an active partner in plan development and their own clinical outcomes.

d. **Medication Therapy Management (MTM).** MTM is a distinct service, or group of services, that optimize therapeutic outcomes for individual patients. These services may be performed by pharmacists or other health care professionals, focusing on a specific patient population and the five core elements of the medication therapy review: a personal medication record; medication-related action plan; intervention and/or referral; documentation; and follow-up.

e. **Pharmacovigilance.** Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problems; it involves the use of pharmacoepidemiological studies.

f. **Prescriptive Authority.** Prescriptive authority is the ability to write prescriptions or orders for medications and supplies in accordance with the provider's individualized scope of practice or clinical privileges.

g. **Prescription Drug Monitoring Program (PDMP).** PDMP is a state-controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 3990 of the Public Health Service Act (42 U.S.C. 280g–3). Generally, these programs require pharmacies registered in their state to enroll and transmit (electronically) records of each dispensing of a controlled substance. States laws vary regarding the definition of controlled substance, requirements for software compatibility, frequency of data transmission, and required patient identifiers.

h. **Radiopharmacy.** Radiopharmacy is the preparation and dispensing of radioactive agents for diagnostic and therapeutic purposes.

i. **Risk Reduction.** Risk reduction is a program that intervenes and educates clinicians on known therapeutic risks to improve prescribing practices, enhance safe medication use, and improve patient outcomes.

j. **Telepharmacy.** Telepharmacy is the integration of telecommunication technology into the delivery and monitoring of pharmaceutical services.

k. **VA Medical Facility Pharmacy.** VA medical facility pharmacy refers to VA prescription dispensing locations.

4. POLICY

It is VHA policy to provide comprehensive, collaborative, and patient-centered pharmaceutical services in VA medical facilities. It is VHA policy that, consistent with federal law, VA pharmacies will participate in state prescription drug monitoring programs (PDMP), as specified in paragraph 10 below.

5. RESPONSIBILITIES

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

(1) Ensuring that each Chief of Pharmacy Services is a licensed pharmacist. ***NOTE:*** *When the Chief, Pharmacy Services position is vacated, a licensed pharmacist must be designated to serve as Acting Chief, Pharmacy Services, until such time that a new Chief is selected.*

(2) Ensuring that the Chief of Pharmacy Services is appropriately graded in accordance with VA Handbook 5005, Appendix 15, Licensed Pharmacist Qualification Standards.

(3) Providing appropriate staff, space, equipment, fixtures, and other resources to enable Pharmacy Services to meet all applicable requirements and standards set by VA and VHA policies; The Joint Commission; Drug Enforcement Administration (DEA); Food and Drug Administration (FDA); and other regulatory bodies. These resources must be sufficient to provide quality and timely services for optimum patient care delivery. For example:

(a) To provide the scope of services required to meet and comply with applicable federal and state laws and regulations, VA and VHA policies, The Joint Commission, and other regulatory bodies.

(b) To provide services to other VA facilities under a sharing agreement, Community-based Outpatient Clinics (CBOCs), and State Veterans Homes based on staffing determinations.

(c) To provide technical support by personnel who are properly classified and encouraged to pursue certification in all instances. Duties performed by technical support personnel will be under the direct supervision, and in certain activities the general supervision (e.g., repetitive functions for which they have been trained and certified), of a licensed pharmacist; as defined in VA medical facility policy.

(4) Ensuring the Chief of Human Resource Management Service, or designee, verifies that each pharmacist's license and pharmacy technician's certification is current and active on a yearly basis.

(5) Ensuring the Chief, Pharmacy Services, has oversight for professional practice for all VA medical facility pharmacists, regardless of the medical facility's organizational structure. This includes, but is not limited to competency assessment; functional statements; direct patient care responsibilities; scope of practice recommendations; and professional practice evaluations for pharmacists with a scope of practice. This oversight is shared with the clinical service chief in those instances where the clinical pharmacist with direct patient care responsibilities is organizationally aligned with another service and with the chief of the clinical service that is ultimately responsible for the care being delivered.

(6) Ensuring there is at least one full time Pharmacy Informaticist/Automated Data Processing Application Coordinator (ADPAC) who is properly trained to support VistA software changes including testing and implementation, pharmacy automation systems, data analytics, and system monitoring and reporting.

(7) Ensuring that medical facilities participating in the transportation and provision of medication to patients in a home health setting develop a local medical facility policy to address the provision of medication in that setting.

b. **Chief, Pharmacy Services or VA Medical Facility Pharmacy Manager.** The Chief, Pharmacy Services or the VA medical facility Pharmacy Manager is responsible for ensuring that patient-oriented pharmaceutical services are consistently provided, in

accordance with VA and local medical facility policies, across all facilities of assigned authority. These services include but are not limited to:

(1) Ensuring the physical security of expired or soon-to-expire medications in each VA medical facility and CMOP, including:

(a) Drug products designated for reverse distribution must be stored in a secure locked area separate from normal inventory (i.e., locked cabinet with limited access to key, controlled substance vault).

(b) Reviewing the expired or soon-to-expire drug inventory when unusual access patterns are noted during security reviews conducted by the Chief of Pharmacy. Examples of unusual access patterns would be employees frequently asking for locked cabinets/drawers to be opened or frequent trips in and out of the controlled substance vault with no clear business need. In the event that discrepancies in expired or soon-to-expire drug inventory are noted, the Chief of Pharmacy should determine whether changes in existing security controls are warranted.

(c) Expired or soon-to-be-expired medications that are controlled substances must be stored and monitored in accordance with VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.

(2) Ensuring inventory tracking of outdated non-controlled substance medications:

(a) Maintaining a running list of non-controlled substance medications held for return for credit in VA medical facility pharmacies as they are removed from current supplies. At a minimum this list must contain drug name and quantity. ***NOTE:*** *The contents of opened units or bottles may be estimated.*

(b) Disposition and accounting of expired or soon-to-be-expired medications that are controlled substances should be accounted for as outlined in VHA Directive 1108.01.

(3) General supervision of all professional and non-professional pharmacy staff.

(4) Controlling access to the pharmacy as specified in paragraph 8.

(5) Planning, organizing, and directing all pharmacy programs.

(6) Providing all communication and administrative support to medical facility management on pharmacy-based activities.

(7) Interacting with Veterans Integrated Service Network (VISN), medical facility, and CMOP management on all pharmacy related fiscal and quality of care issues. ***NOTE:*** *The Chief, Pharmacy Services is to coordinate VISN communications with the VISN Pharmacist Executives (VPE). The VPE is the liaison for the communication of issues and actions required of PBM Services.*

(8) Ensuring that all pharmacists understand and accept their responsibility to support safe, evidence-based, and cost-effective use of medications.

(9) Ensuring that their VA medical facility pharmacy is adequately staffed with appropriate administrative support commensurate with the size and scope of the service.

(10) Ensuring each pharmacy located in a state with a PDMP transmits data in accordance with the requirements in this directive (see paragraph 10).

(11) Ensuring compliance with VA policies and DEA regulations regarding controlled substance accountability requirements.

(12) Ensuring that technologies and equipment are up-to-date and pharmacy staff are adequately trained to operate the equipment.

(13) Ensuring compliance with VA fiscal and logistics requirements including:

(a) Reconciliation of pharmaceutical orders with items delivered, noting any discrepancies;

(b) Review of the receiving invoice/packing slip for signature and date. ***NOTE:*** *There must be evidence of receipt of all goods ordered via VA Form 1358, Obligation or Change in Obligation; purchase cards; VA Form 2237, Request, Turn-In and Receipt for Property or Services; or similar to justify payment.*

(c) The review of purchase card orders first received by the warehouse to validate that they have signatures on the receiving report from warehouse staff or by the reviewing pharmacy personnel. ***NOTE:*** *Purchase card orders received directly in pharmacy must be signed (invoice/packing slip) by the responsible pharmacy staff member.* See *VA Handbook 7002/1, Part 4, which requires designated receiving individuals to certify receipt, inspection and acceptance of goods ordered and received.*

(d) Review of the Fiscal B09 report and reconciliation of that report with VA Form 1358 to ensure that the pharmacy is making correct payments for what is received and there is documented evidence (signature and date of review) that it has been completed. ***NOTE:*** *The Fiscal B09 report is generated weekly from the Financial Services Center, Austin, Texas and is similar to invoices that are processed through the on-line certification process or purchase card statement, with the exception that it is a summary of several invoices. VA Financial Policy XVI, Chapter 1 requires reconciliation of billing statements, verification of items ordered being received, and certification as to accuracy including maintenance of supporting documentation (e.g., receipts, invoices and packing slips).*

(e) Providing a monthly report, with adequate documentation, to the Chief of Fiscal Service stating the VA Form 1358s and B09 reports were reconciled and noting any unresolved discrepancies.

(f) Maintaining separation of duties so that different pharmacy staff members place and receive an order. ***NOTE:*** *The same employee cannot place and receive a given order. See the Financial Management and Accounting Systems Alert Volume 2013, issue 001, the standard operating procedures for the B09 reconciliation process at* http://vaww.cfo.med.va.gov/173/Alerts_13/001_2013_B09_reconcil_sop.pdf. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

(g) Different staff members must be involved in the Form 1358 process including establishing, approving, and obligating the 1358, and certifying (receiving) goods ordered on the 1358. ***NOTE:*** *The staff member that establishes the 1358 cannot receive any orders they themselves placed to the prime vendor via the 1358.*

(14) Ensuring, during periods of construction/renovation, that the Chief, Engineering Service is in compliance with VHA Directive 2011-036, Safety and Health During Construction, or subsequent policy issued, for the general protection of pharmacy staff, assurance of product stability and sterility (during product manufacture/manipulation), and maintaining an appropriate environment for pharmacy inventory.

(15) Ensuring the annual wall-to-wall inventory is completed and entered into the PBM SharePoint site by the required due date communicated by PBM Hines Office each calendar year.

c. **Consolidated Mail Outpatient Pharmacy Director.** The CMOP Director, or designee, is responsible for:

(1) Ensuring the physical security of expired or soon-to-expire medications in each VA medical facility and CMOP, including:

(a) Drug products designated for reverse distribution must be stored in a secure locked area separate from normal inventory (i.e., locked cabinet with limited access to key, controlled substance vault).

(b) Reviewing the expired or soon-to-expire drug inventory when unusual access patterns are noted during security reviews conducted by the Chief of Pharmacy. Examples of unusual access patterns would be employees frequently asking for locked cabinets/drawers to be opened or frequent trips in and out of the controlled substance vault with no clear business need. In the event that discrepancies in expired or soon-to-expire drug inventory are noted, the Chief of Pharmacy should determine whether changes in existing security controls are warranted.

(c) Expired or soon-to-be-expired medications that are controlled substances must be stored and monitored in accordance with VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.

(2) Ensuring inventory tracking of outdated non-controlled substance medications:

(a) Maintaining a running list of non-controlled substance medications held for return for credit in VA medical facility pharmacies as they are removed from current supplies. At a minimum this list must contain drug name and quantity. ***NOTE:*** *The contents of opened units or bottles may be estimated.*

(b) Disposition and accounting of expired or soon-to-be-expired medications that are controlled substances should be accounted for as outlined in VHA Directive 1108.01.

d. **Associate Chief, Pharmacy Services.** The Associate Chief, Pharmacy Services or the Associate Chief, Clinical Pharmacy Services as assigned by the Chief, Pharmacy Services is responsible for overseeing all professional and clinical pharmacy activities. These may include, but are not limited to:

(1) CMM services;

(2) Direct patient care services (e.g., Anticoagulation Clinic, Medication Management Clinic, etc.) where appropriate and feasible;

(3) Collaboration with State Veterans Homes;

(4) Contractual agreements associated with non-VA retail prescription services;

(5) The procurement, storage, distribution, and reverse distribution of drugs and supplies. ***NOTE:*** *This includes specialty programs (e.g., research, drug detoxification and treatment, same day surgery, etc.);*

(6) Patient education,

(7) VISN or medical facility telepharmacy or prescription refill call centers that are under pharmacy supervision;

(8) Drug administration when authorized;

(9) Pursuing Scopes of Practice for pharmacists, when appropriate;

(10) Coordination of all drug and supply dispensing from CMOP and specialty pharmacy services; and

(11) The provision of drug information and consultative services to all patients and health care professionals.

6. LICENSURE REQUIREMENTS

a. Each pharmacist must maintain a current, active, and unrestricted license in a state, territory of the United States, or the District of Columbia.

b. The Chief of Human Resource Management Service must verify that each pharmacist's license is current, active, and unrestricted each year.

c. The pharmacist's license and current renewal must be readily available for review. ***NOTE:*** *Credentialing of pharmacists using VetPro, an internet-enabled system that facilitates completion of a uniform, accurate, and complete credentials file, is required.*

d. It is the pharmacist's responsibility, whether seeking employment or already employed by VA, to immediately inform the Chief, Pharmacy Services and the Chief, Human Resource Management Service if their license has been suspended, revoked, or restricted in any way.

e. In those instances where a clinical pharmacist position is aligned within a clinical service (e.g., Primary Care, Specialty Care, Pain Management, etc.), the signatures of both the clinical section's service chief, to which the clinical pharmacist is aligned, and the Chief, Pharmacy Services, are required for all recommendations for the pharmacist's scope of practice.

f. A few, but not all, VA medical facility pharmacies are licensed by a state entity. VA participation in State PDMPs will not be predicated on the requirement to maintain state licensure. ***NOTE:*** *There is no requirement for VA medical facility pharmacies to be licensed by a state entity.*

7. STAFFING

a. All pharmacy service positions, both professional and non-professional, must be assigned to and under the general supervision of the Chief, Pharmacy Services. This individual is responsible for the overall operation of the service, and therefore must be a licensed pharmacist. In the Chief's absence, the Associate Chief (preferably), or another licensed pharmacist, should be designated as Acting Chief of Pharmacy Services, as appropriate.

b. An Associate Chief, Pharmacy Services position must be included in the Pharmacy Service's organizational chart regardless of facility complexity. This position is necessary due to the diversity of professional pharmacy services, responsibility for the management of a significant percentage of the VA medical facility's operational budget, and the need for succession planning.

c. A full-time Administrative Officer or secretary position must be provided to the Chief of Pharmacy Services to effectively carry out office requirements.

d. Additional licensed Clinical Pharmacists will be provided to supervise and perform all professional functions.

8. SECURITY

a. Physical security of the pharmacy must be maintained in accordance with current security procedures as defined in VA Handbook 0730, Security and Law Enforcement, or subsequent policy issue.

b. For internal security purposes, the issuance of door keys, security cards, or numerical combination access that allow entry into pharmacy service is to be restricted by the Chief, Pharmacy Services, to employees who require access.

c. A licensed pharmacist must be on duty during all hours of pharmacy operation.

d. Strict accountability of security access must be maintained and documented. Documentation will be based on the local VA medical facility system and its capabilities. For example, monthly printouts of access points should be reviewed for concerns such as unnecessary access to locations of non-assignment, off tour entry by unscheduled staff members, and the like.

e. All keys and security cards must be retrieved and general access combinations must be changed when an employee with access leaves pharmacy employment. ***NOTE:*** *Those services with scrambler pad access and individual numerical codes must terminate the employee's personal code on the employee's last working day as part of the reassignment or clearance process.*

f. Security cards or numerical combination access codes for entry into controlled drug vault(s) and safe(s) must be limited to those pharmacy employees requiring access. Numerical codes must be changed in accordance with VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), or subsequent policy issue.

g. If the controlled substance vault has a day gate, it must have a locking mechanism and remain in a closed position when the vault door is open. The use of an object to prop the door open or hinder the locking mechanism is prohibited. ***NOTE:*** *Local medical facility policy and procedures must address this security issue.*

h. Access doors to Pharmacy Services must be secured at all times. Entry into any VA medical facility pharmacy by non-pharmacy employees must be strictly controlled by the Chief, Pharmacy Services, or supervisory designee(s). Local medical facility policies and procedures must address the issue of pharmacy access by non-pharmacy personnel and patients.

i. Any issuance of security cards and keys must be tightly controlled in accordance with VA medical facility policy. Keys designated for pharmacy access are specially mastered keys; not mastered to the facility grandmaster and replaceable only at the request of the Chief, Pharmacy Services.

9. SPACE

a. In keeping with the mission of the VA medical facility, space is to be provided for the administrative, professional, clinical, distributive, and other specialty pharmacy activities as outlined in VA Handbook 7610, Chapter 268, Pharmacy Service, see http://www.cfm.va.gov/til/space/SPchapter268.pdf and the Office of Construction and Facilities Management Design Guides (PG-180-12), see http://www.cfm.va.gov/til/dGuide.asp.

b. Particular attention is to be directed toward maintaining appropriate temperature in order to protect the integrity of medications in all pharmacy storage areas. Failure to maintain medication integrity is hazardous to patient safety.

c. Most medications must be maintained per FDA labeled recommendations (as defined by the United States Pharmacopeia [USP]) for "controlled room temperature". That means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20º to 25ºC (Centigrade) (68º to 77ºF [Fahrenheit]); the result is a mean kinetic temperature calculated to be not more than 25º; and it allows for short term excursions between 15º and 30ºC (59º and 86ºF) that are experienced in pharmacies, hospitals, and warehouses. ***NOTE:*** *The pharmacy spaces have a combination of products stored in the same location and control of temperature should follow the strictest temperature requirement (68º to 77ºF)* o*f the medications stored in that location.*

d. There is a lack of specific data regarding temperature or humidity requirements for USP 797 (sterile compounding) cleanrooms. Ideally, the controlled compounding rooms should be 66ºF +/-2ºF to ensure employee comfort when fully garbed. Relative humidity (RH) recommendations should be between 30 and 65 percent RH.

10. PARTICIPATION IN STATE PRESCRIPTION DRUG MONITORING PROGRAMS

a. VA pharmacies must participate in active PDMPs that are compatible with VA software. Although state PDMP laws vary, VA will transmit the same information, as described below, to all states' PDMPs.

b. VA pharmacies must comply with the following:

(1) VA pharmacies will enroll in the state program where the VA medical facility is geographically located.

(2) VA pharmacies will only transmit the data outlined in paragraphs 10.b.(3) to 10.b.(5) for substances identified in 21 CFR part 1308 as schedules II through V controlled substances.

(3) VA pharmacies will transmit prescriber information, such as name and DEA number.

(4) VA pharmacies will transmit patient demographic information, such as name, permanent address, date of birth and patient identification number.

(5) VA pharmacies will transmit the following prescription data:

(a) The prescription number,

(b) The date of origin (i.e., issuance) of the prescription,

(c) The date of dispensing (i.e., release date),

(d) The number of authorized refills,

(e) The prescription's origin code,

(f) The National Drug Code for the drug dispensed,

(g) The quantity of drug units dispensed,

(h) The generic or brand name, when the formulation contains multiple agents, of the drug dispensed,

(i) The drug dosage; and

(j) Whether the substances were dispensed as a new or refill of a prescription. ***NOTE:*** *This will be accomplished by using Veterans Health Information Systems and Technology Architecture (VistA) option 'View/Edit SPMP State Parameters' [PSO SPMP STATE PARAMETRS] to establish the parameters for each respective state name, the corresponding version of the American Society for Automation in Pharmacy standard used to transmit data, the frequency of transmissions, and the state's recipient IP address to which the transmission will be directed.*

c. VA pharmacies are not authorized to transmit prescription data for substances that are not identified in 21 CFR part 1308 as schedules II through V controlled substances.

d. VA pharmacies are prohibited from marking non-controlled medications as controlled substances in the VistA "DEA, SPECIAL HDLG" field solely for the purpose of inventory tracking (e.g., high cost medications).

e. VA pharmacies are prohibited from changing the controlled substance schedule of a drug in VistA from the federal definition.

f. VA pharmacies will not transmit prescription information about prescriptions dispensed by non-VA entities, even if VA has a record of those prescriptions.

g. VA pharmacies will transmit prescription data to PDMPs on a daily basis.

h. VA pharmacies will receive rejected prescription data from the state PDMP.

i. VA pharmacies will reconcile rejected prescription data within 3 business days, as long as the information is readily available from VA sources.

j. CMOPs are not required to transmit prescription data to a state's PDMP. ***NOTE:*** *Data pertaining to VA controlled substance prescription dispensing from the CMOP will be transmitted to state PDMPs by the originating VA medical facility.*

k. The Chief of Pharmacy Services or designee will notify the PDMP, either by telephone or email, in the event of a disaster or other contingency that disrupts the

normal operations for greater than three business days. Documentation should be maintained noting when the PDMP was notified, how long the disruption lasted, and when transmission was re-started.

11. PROVISION OF MEDICATION IN A HOME HEALTH SETTING

In collaboration with Home Based Primary Care (HBPC), Mental Health Intensive Case Management (MHICM), or other home-based programs, the facility VA pharmacy will establish a local policy that identifies, at a minimum, the following:

a. The medical facility staff authorized to;

(1) Transport and administer medications and supplies to a patient's home, and

(2) Accept from pharmacy and deliver to the patient's home prescription(s) and supplies specifically ordered and dispensed for that patient.

b. A signed medication order or prescription, verified by a pharmacist, for all medications administered to the patient. ***NOTE:*** *This requirement does not apply to medications (e.g., influenza vaccine, etc.) that can be administered pursuant to a medical facility approved protocol which does not require a provider's order and pharmacist verification.*

c. Clearly defined storage and transportation requirements to include:

(1) Specific requirements to ensure medications are stored at the appropriate temperature while in transit (e.g., refrigeration, preventing exposure to direct heat or sunlight),

(2) Ensuring that security measures are reviewed and approved by the Police and Security Service,

(3) Locked storage containers for transport that do not identify their contents.

(4) Locked refrigerated/cooled storage containers, when required.

(5) Locked medication storage containers are to be stored out of plain sight,

(6) Unused or partially used medications taken to the home for the specific purpose of administration by VA staff should not be left in the patient's home, and

NOTE: *Staff must return partially used medications (e.g., partial vial, intravenous solutions, etc.) to the facility for proper disposal per VA medical facility policy. However, medical facility staff will <u>not</u> accept unwanted/unneeded patient specific medications and dispensed prescriptions for disposal when visiting the patient.*

(7) A requirement for the return of non-patient specific medications to an established VA medical facility if the medication has not been administered by the end of the VA staff person's shift, as stated in local VA medical facility policy.

d. A procedure for the pharmacy to dispense medications that can be administered pursuant to a facility approved protocol which does not require processing through the VistA system's pharmacy application software (e.g., Influenza vaccine to an authorized healthcare provider). This process should include a documented chain of custody that can be stored and retrieved at a later date, and appropriate medication labeling requirements.

e. A documented chain of custody for all prescription medications transported by VA staff from pharmacy to the patient. The form must include a final signature by the patient, or authorized surrogate, accepting control of the prescription(s). The signed chain-of-custody forms should be maintained by Pharmacy Services for a period of 2 years.

f. Requirements to assure the integrity of the medication prior to administration (e.g., examination for particulate matter, discoloration; and labeling requirements).

g. Assessment of staff competency for the appropriate safe handling and administration of medications.

h. For those VA medical facilities that support the practice of allowing medical facility staff, such as Rural Health Care Providers, to transport and administer medications to a patient in their home, a list of non-patient specific medications that can be transported and administered as deemed clinically appropriate by the staff. This list of medications must be approved by the VA medical facility's Pharmacy and Therapeutics Committee, and sanctioned by the Chief of Staff.

12. REFERENCES

a. P.L. 97-255

b. U.S.C. §§ 7301, 7305 and 7401.

c. 38 C.F.R. 1.483, 1.515 and 17.38.

d. VA Directive 0730, Security and Law Enforcement, dated December 12, 2012.

e. VA Handbook 5005/36, Part II, Appendix G15, "Licensed Pharmacist Qualification Standard GS-660," dated August 16, 2010.

f. VA Handbook 7002/1, Part 4; "Accounting Requirements," dated April 14, 2011.

g. VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.

h. VA Office of Construction and Facilities Management, Design Guides (PG-18-12): https://www.cfm.va.gov/til/dGuide.asp.

i. “Sound Medication Therapy Management Programs,” Consensus Document, February 15, 2006, Journal of Managed Care Pharmacy.

j. 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.

PROGRAM GUIDANCE

1. PHARMACY SERVICES

a. **Distributive Services.** Distributive services include the provision of outpatient and inpatient pharmaceutical services and approved products. This includes ordering, storing, disposal, distributing, supporting, administering, dispensing, and maintaining proper records for all pharmaceuticals, including but not limited to, emergency drug caches, controlled substances, parenteral therapy, and investigational drugs.

b. **Clinical Pharmacy Services.** Clinical pharmacy services include the provision of CMM to outpatients and inpatients that is intended to achieve optimal patient care outcomes. Clinical pharmacy services include both direct and non-direct patient care activities and may be included in the role of all clinical pharmacist positions, as appropriate. 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. Clinical pharmacy services shall optimize therapeutic outcomes through the inclusion of pharmacist-based direct patient care in a variety of ways, including:

(1) Performing patient health assessments,

(2) Managing high-cost and specialty medications and supplies,

(3) Evaluating and monitoring of patient response to drug therapy,

(4) Implementing risk reduction and the prevention of adverse events,

(5) Providing education and training to patients,

(6) Participating in team or interdisciplinary rounds such as Home Based Primary Care,

(7) Providing CMM services, and

(8) Prescriptive authority.

c. **Formulary Management Services.** Formulary management services include the coordinated review of medication use, in collaboration with the VA medical facility's Pharmacy and Therapeutics (P&T) Committee and VISN P&T or similar committee.

d. **Pharmacy Procurement and Contracting Activities.** Procurement and contracting activities involve the purchase of drugs, supplies (both drug related and operational), automation and services. There must be a clear separation of duties to minimize the risk of fraud or loss of property. Assignment of duties, such as: authorizing, approving, and recording transactions; receiving assets; approving cardholder statements; making payments; certification of funding; and reviewing or auditing, need to be assigned to separate individuals to the greatest extent possible.

NOTE: *For clarification, one person cannot be the cardholder and approving official for the same transaction. For further information see paragraph 12.h., References.*

e. **Specialty Pharmacy Services.** Specialty pharmacy services are those services that require special expertise such as radiopharmacy, research pharmacy, direct patient care in specialty clinics and inpatient environments, etc.

f. **Pharmacy Practice Training Programs.** Pharmacy practice training programs are essential to the recruitment, retention, and development of VA pharmacists and pharmacy technicians. Pharmacy student and pharmacy technician student training programs should be promoted through VA affiliation agreements with accredited schools. VA pharmacy residency sites must be accredited by the American Society of Health-System Pharmacists.

2. OPERATIONAL EFFICIENCIES

a. VHA pharmacy managers are responsible for being good financial stewards by assuring that resources allocated to Pharmacy Service are being utilized in a manner that delivers maximum benefit to the patient and guarantees safety, proper medication use, and the delivery of clinical care that closes gaps in any unmet patient need.

b. In order to achieve operational efficiency, clinical pharmacists and pharmacy technicians must function to the fullest extent permissible by licensure, scope of practice, certifications and training. Pharmacy Services must conduct assessments of their current practices, regardless of their area of assignment, to assure that they are in accordance with identified best practices. Additionally, automation and computer technology should be instituted wherever possible to maximize safety, improve operational efficiency, and enable the reassignment of pharmacy staff to expand pharmacy activities. In addition to staff reassignments, telephone automation can expand the use of clinical pharmacist staff at remote facilities and locations (e.g., initiate telework arrangements to improve efficiency and processes). Operational efficiencies that can be explored should include, but are not limited to:

(1) Utilization of virtual technology to provide patient counseling from the centralized pharmacy to designated areas such as the emergency department,

(2) Centralized and remote location prescription processing,

(3) Utilization of automated cart delivery systems,

(4) Consolidation of VISN processes (e.g., review of non-formulary drug requests, etc.), and

(5) Centralization of telephone answering services.

c. Strategies outlined below have been shown to enable Clinical Pharmacist Specialists (CPS) to take on additional clinical roles within the medical facility;

demonstrating improvements in patient care, medication safety, and overall cost per patient.

(1) Institute and enforce VA medical facility policy limiting routine prescription refills in the medical facility's urgent care (Emergency Department) and at the Outpatient Pharmacy window.

(2) Use of prepackaged or starter supplies of urgent medications (e.g., antibiotics, pain medications, etc.) in designated areas such as the Emergency Department which can be dispensed directly to the patient by a licensed independent practitioner (LIP) in off hours of operation.

(3) The purchasing of pre-made or frozen products, despite the sometimes higher unit cost, leading to an enhanced return-on-investment which results from the redirected clinical pharmacy activities.

(4) Assess all activities currently being performed by CPSs that can be transferred to pharmacy technicians. Reassignment of these activities then allows for the most effective use of clinical pharmacist staff.

3. AVAILABILITY OF PHARMACY SERVICES

a. Overall pharmacy services provided should be sufficient to meet the needs of the patient and the VA medical facility's health care staff. Where inpatient pharmacy services are not provided on site 24-hours a day, 7-days a week, a telepharmacy and/or "On-Call" duty roster, that meet the need of the VA medical facility during off hours, must be established and maintained in medical facility policy. Entrance to the pharmacy by anyone other than pharmacy personnel must be permitted only in emergencies and according to strict controls established by VA medical facility policy and based on The Joint Commission standards.

c. Outpatient pharmacy service hours of operation must be sufficient to support normal clinic hours of operation. When not open for normal operation, back-up or contracted services must be available to provide emergently needed prescriptions.