

PHARMACY GENERAL REQUIREMENTS

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides policy and guidance for the management of the Department of Veterans Affairs (VA) Pharmacy Program.

2. SUMMARY OF MAJOR CHANGES. This new VHA Handbook incorporates aspects of the Pharmacy practice previously found in Policy Manual, M-2, Part VII, Chapter 1. The most significant change from the former policy is the inclusion of a defined scope of clinical pharmacy practice for the purpose of standardization.

3. RELATED DOCUMENTS. VHA Handbook 1108.1, VHA Handbook 1108.2, VHA Handbook 1108.3, VHA Handbook 1108.04; VHA Handbook 1108.05, and VHA Handbook 1108.06.

4. RESPONSIBLE OFFICE. The Office of Patient Care Services' Pharmacy Benefits Management Strategic Health Care Group (119) is responsible for the contents of this Handbook. Questions may be addressed to the Chief Consultant at (202) 461-7326.

5. RESCISSIONS. VHA Manual M-2, Part VII, Chapter 1, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of April 2013.

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PHARMACY GENERAL REQUIREMENTS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides policy, responsibilities and guidance for the management of Pharmacy practice.

2. BACKGROUND

Pharmacy Services is an essential component in the Department of Veterans Affairs (VA) integrated health care delivery 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 area of professional pharmacy practice and post-graduate pharmacist education; external organizations consider VA pharmacy practice the professional benchmark in many areas of care. This Handbook is intended to identify the basic institutional support requirements for VA Pharmacy Services to ensure both consistency of care throughout the VA and the continued advancement of VA pharmacy as an industry leader.

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 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, including Pharmacy Site Manager, Pharmacist Director, etc.

b. **Medication Therapy Management.** Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product.

c. **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 encompasses the use of pharmacoepidemiological studies.

e. **Pharmacoepidemiology.** Pharmacoepidemiology is the study of the use and the effects of drugs in large groups of people. It can be viewed as an epidemiological discipline with particular focus on drugs.

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.

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

h. **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.

i. **Telepharmacy.** Telepharmacy is the integration of telecommunication technology into the delivery of pharmaceutical services.

4. SCOPE

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.

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

b. The clinical activities include: patient education, medication therapy management, drug information and consultative services, patient assessment, drug administration, and prescriptive authority (in specialized cases under a Scope of Practice Agreement). These distributive, clinical and additional pharmacy services include the provision of care to patients at VA Community-based Outpatient Clinics (CBOC).

5. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

The Medical Center Director is responsible for:

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

b. Providing the appropriate staff, space, equipment, fixtures, and other resources that enable Pharmacy Service to meet all requirements of: VA Handbooks, Manuals, and Directives; The Joint Commission (TJC); 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.

c. Ensuring the VA pharmacies is adequately staffed:

(1) To provide the scope of services required in accordance with: Federal and state regulations; VA Handbooks, Manuals, and Directives; TJC; and other regulatory bodies.

Staffing for services provided to other VA facilities under a consolidation agreement, CBOC's and State Veterans Homes are to be included in the staffing determination.

(2) By technical support personnel. Support personnel need to be defined, properly classified and encouraged to pursue certification in all instances. Duties performed by support personnel will be under the direct supervision of a licensed pharmacist.

d. Ensuring the Chief of Human Resource Management Service verifies that each pharmacist's license is current each year.

6. RESPONSIBILITIES OF THE CHIEF, PHARMACY SERVICES

The Chief, Pharmacy Services is responsible for ensuring that patient oriented pharmaceutical services are consistently provided, in accordance with National Formulary Policy, across all facilities of assigned authority. These services include, but are not limited to:

- a. Planning, organizing, and directing all pharmacy programs.
- b. Providing all communication and administrative support to the medical center management.
- c. Interacting with VISN, medical center 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 Formulary Leader (VFL) or PBM Manager (PBMMGR). The VFL or PBMMGR is the liaison for the communication of issues and actions required of the PBM Service.*
- d. Ensuring that all pharmacists understand and accept their responsibility to support safe, evidence-based, and cost-beneficial use of medicines.
- e. Ensuring that all pharmacies are adequately staffed with appropriate administrative support commensurate with the size and scope of the service.

7. LICENSURE REQUIREMENTS

Pharmacist licensure requirements and conditions are as follows:

- a. Each pharmacist must maintain a current, active 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 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 in accordance with VHA policy.

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 any pharmacist license has been suspended or revoked.

e. In those instances where medical center pharmacist positions are not listed on the Pharmacy Organizational Chart (e.g., Pharmacists who work for Managed Care, Pain Management, etc), the Chief, Pharmacy Services is responsible for the professional practice standards and boarding actions for these positions.

8. RESPONSIBILITIES OF THE ASSISTANT CHIEF, PHARMACY SERVICES

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

- a. Disease state management services;
- b. Direct patient care services (e.g., Anticoagulation Clinic, Medication Management Clinic, etc.) where appropriate and feasible;
- c. Collaboration with State Veterans Homes;
- d. Contractual agreements associated with non-VA retail prescription services,
- e. The procurement, storage, and distribution of drugs and supplies; **NOTE:** *This includes specialty programs (e.g., research, Drug Detoxification and Treatment, same day surgery, etc.).*
- f. Patient education;
- g. Medication therapy management;
- h. VISN or medical center telepharmacy or prescription refill call centers;
- i. Drug information and consultative services;
- j. Drug administration when authorized;
- k. Pursuing Scopes of Practice for pharmacists, when appropriate;
- l. Coordination of all drug and supply dispensing from CMOP; and
- m. The provision of drug information and consultative services to all patients and health care professionals.

9. 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 outpatient and inpatient drug therapy that is intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process. Clinical pharmacy services shall optimize therapeutic outcomes through the inclusion of pharmacist-based direct patient care by:

- (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 interdisciplinary teams such as Home Based Primary Care; and
- (7) Coordinating medication therapy with other care management services.

c. **Formulary Management Services.** Formulary management services include the coordinated review of medication use, through the medical center's Pharmacy and Therapeutics (P&T) Committee or VISN P&T Committee.

d. **Specialty Pharmacy Services.** Specialty pharmacy services are those services that require special expertise such as radiopharmacy, research pharmacy, one-to-one patient care, etc.

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

10. AVAILABILITY OF PHARMACY SERVICES

Pharmacy services provided should be sufficient to meet the needs of the patient and the health care staff:

a. Where inpatient pharmacy services are not provided 24-hours a day, 7-days a week, a telepharmacy and/or "On-Call" duty roster, that meets the needs of the medical center during off hours, must be developed and maintained. Entrance to the pharmacy by anyone other than pharmacy personnel must be permitted only in emergencies and according to strict controls established by local medical center policy and based on TJC standards.

b. 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.

11. 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, who must be a licensed pharmacist. This individual is responsible for the overall operation of the service, and therefore must be a licensed pharmacist. In the Chief's absence, the Assistant Chief, or another licensed pharmacist, is to be designated to the Acting Chief of Pharmacy Services.

b. An Assistant Chief, Pharmacy Services position needs to 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 medical center'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 the necessary administrative functions.

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

12. SECURITY

a. Physical security of the pharmacy must be maintained in accordance with current security regulations as defined in VHA Handbook 0710.01.

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. **NOTE:** *A licensed pharmacist must be on duty for the pharmacy to be open.*

c. Strict accountability of security access must be maintained and documented.

d. All keys and security cards must be retrieved, and general access combinations must be changed when an employee with access leaves pharmacy employ. **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.*

e. Security cards or numerical combination access codes for entry into controlled drug vaults and safes must be limited to those pharmacy employees requiring access, and must be changed in accordance with VHA Handbook 1108.1, Controlled Substances (Pharmacy Stock).

f. 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 center policy and procedures must address this security issue.*

g. Access doors to Pharmacy Services must be secured at all times. Entry to pharmacy services by non-pharmacy employees must be strictly controlled by the Chief, Pharmacy Services, or a supervisory designee. Local medical center policies and procedures must address the issue of pharmacy access by non-pharmacy personnel and patients.

h. Any issuance of security cards and keys must be tightly controlled in accordance with local medical center policy. Keys designated for pharmacy are special keys, not mastered to the facility grandmaster, and replaceable only at the request of the Chief Pharmacist.

13. SPACE

In keeping with the mission of the VA 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.

14. REFERENCES

a. "Sound Medication Therapy Management Programs," Consensus Document, February 15, 2006, Journal of Managed Care Pharmacy.

b. VHA Handbook 5005, Part II, Appendix G-15, "Licensed Pharmacist Qualification Standard," dated March 15, 2006.

c. VHA Handbook 0710.01.