

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-2, Part VII
Chapter 9

January 19, 1994

1. Transmitted is a revision to the Department of Veterans Affairs, Veterans Health Administration, Manual M-2, "Clinical Affairs," Part VII, "Pharmacy Service," Chapter 9, "Drug Controls and Accountability." Brackets have not been used to indicate changes.

2. The principal change is:

Paragraph 9.06: Changes the Quality Assurance Committee to Quality Improvement Committee and redefines its function.

3. Filing Instructions

Remove pages

Insert pages

9-1 through 9-3

9-i through 9-ii

9-1 through 9-3

4. RESCISSIONS: M-2, Part VII, Chapter 9, dated March 28, 1991.

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RESCISSIONS

The following material is rescinded:

Manual

M-2, Part VII, Chapter 9, dated March 28, 1991.

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CHAPTER 9. DRUG CONTROLS AND ACCOUNTABILITY

9.01 POLICY

Pharmacy Service provides proper accountability and drug controls. Assurance that proper drug controls are achieved requires the establishment of standards, procedures, and continual review. This includes the development of a systematic quality improvement review process that can be applied to the prescribing, dispensing, and Drug Utilization Review components of the Department of Veterans Affairs (VA) health care system.

9.02 DEFINITION

a. In the practice of modern pharmacy, control of drug use, as well as control of the actual physical drug, is essential. Drug use control includes:

- (1) Drug distribution,
- (2) Therapeutic monitoring,
- (3) Provision of drug information,
- (4) Drug usage evaluation,
- (5) Intervention to change prescribing habits,
- (6) Consultative services, and
- (7) Other measures designed to ensure the safe and efficacious use of drug therapy.

b. Drug Control and accountability must include non-distribution as well as distributive aspects of drug use control.

9.03 FORMS CONTROL

Pharmacy Service is responsible for the storage and issuance of VA Forms 10-2577d, Prescription Forms, and VA Forms 10-2321, Controlled Substance Orders. Upon issuance, local control and use of these forms will be the responsibility of the prescriber, or authorized user.

9.04 INVENTORY CONTROL

- a. Documents that verify inventory receipts are maintained.
- b. Mechanisms to document an audit trail, from receipt of drugs to administration in patient care, should be developed. Use of automatic data processing is encouraged.

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9.05 MEDICATION MANAGEMENT SYSTEMS

The Medication Management Systems used to distribute medication in a medical center may be numerous. They include, but are not limited to, those described in chapter 3. Whatever system or systems a medical center uses, the key requirement is that internal controls are established and continual internal revisions of the system are conducted.

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a. Pharmacy Service supports VA commitment to quality patient care as the primary objective of service.

b. Pharmacy Service has established a Quality Improvement Committee at each VA medical center. The function of the Committee is to improve the quality of pharmacy services locally and to assure that pharmacy services are consistent with the professional standards, guidelines, and technical assistance bulletin cited in Chapters 2 and 3, paragraphs 2.08 and 3.04.

(1) Pharmacy Service has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care services and for resolving identified problems.

(2) The quality and appropriateness of patient care services are monitored and evaluated in all major clinical functions of Pharmacy Service. Non-distributive (clinical) as well as distributive functions are monitored. Monitors should be patient outcome oriented when possible.

(3) When problems are identified, actions are taken to resolve those problems, and the effectiveness of the actions taken are evaluated.

(4) All findings and conclusions are documented and reported.

(5) The actions taken and information about the impact of the actions taken are documented and reported.

c. As pharmaceutical care represents a medical intervention provided to virtually all patients treated in VA facilities, and as it often carries a degree of risk, it is recognized to be an important aspect of patient care. Interdisciplinary planning, including Pharmacy Service and the services prescribing pharmaceuticals, is strongly encouraged for all monitoring and evaluation of the quality and appropriateness of pharmaceutical agents. This may include involvement in the identification of appropriate monitors, the development of criteria and clinical indicators, as well as planning actions which are identified as needed. Medical centers are encouraged to invite Pharmacy Service participation at all medical center-wide committees which address issues pertaining to the utilization of pharmacy services or the use of pharmaceuticals. These committees may include, but are not limited to, the Quality Improvement Committee, the Utilization Review Committee, the Infection Control Committee, and the Drug Use Evaluation Committee.

d. Adverse Drug Events are monitored and trended by the Pharmacy Service representative to the medical center Pharmacy and Therapeutics (P&T) Committee. Reporting of adverse drug events will be conducted as outlined in M-2, Part I, Chapter 3.

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e. Medication errors originating in Pharmacy Service are monitored and trended. Medication errors are categorized by type (e.g., unit dose, IV, window, or mail out). Action is taken to identify and correct contributing factors to medication errors. Such action is documented and evaluated for effectiveness. Medication errors are reported as required by Veterans Health Administration (VHA) Supplement, MP-1, Part I, Chapter 2, change 43.

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f. Pharmacy Service participates in and facilitates drug use evaluation studies conducted by the medical staff. The role of the pharmacist in drug use evaluation and patient care audits is outlined in the professional standards American Society of Hospital Pharmacists (ASHP) Guidelines on the Pharmacist's Role in Drug Use Review and Patient Care Audits. (American Journal of Hospital Pharmacy 1981; 38:1042-1043).

g. Pharmacy Service participates in Boards of Investigation where incidents may have been precipitated by drug therapy or medication errors.

h. All quality improvement information is considered confidential as outlined by 38 United States Code (U.S.C.) 5705. The use of provider specific quality improvement information in disciplinary actions is strictly prohibited. When quality improvement studies indicate that there may be a provider-associated problem, data must be re-collected through an administrative review process. In this process, information is collected in a fair and representative sampling process.

i. Pharmacy Service maintains a Quality Control Program which includes, but is not limited to:

(1) Pharmacy Service IV additive programs have quality control programs in place as outlined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation standards and previous recommendations of the National Coordinating Committee on Large Volume Parenterals.

(2) Where potential pharmaceutical defects have been noted, a Standard Form 380, Reporting and Processing Medical Material Complaints/Quality Improvement Report, is generated by Pharmacy Service and referred to the Office of Acquisition and Materiel Management.

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