

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 2, "Administration." Brackets have not been used to indicate changes.

2. Principal changes are:

a. Paragraph 2.01: Add policy statement as 2.01 and renumber paragraphs accordingly.

b. Paragraph 2.07: Include statement that Pharmacy Service should be in compliance with relevant standards of ASHP (American Society of Hospital Pharmacists).

c. Paragraph 2.08: Subparagraph e increases the emphasis on the proper storage of neuromuscular blocking agents.

3. Filing Instructions

Remove pages

Insert pages

2-1 through 2-5

2-i through 2-ii

2-1 through 2-5

4. RESCISSIONS: M-2, Part VII, Chapter 2, dated March 28, 1991, and change 1, dated June 8, 1993.

S/ by Dennis Smith for
John T. Farrar, M.D.
Acting Under Secretary for Health

Distribution: RPC: 1342
FD

Printing Date: 1/94

CONTENTS

CHAPTER 2. ADMINISTRATION

PARAGRAPH		PAGE
2.01	Policy	2-1
2.02	Scope	2-1
2.03	Organization	2-1
2.04	Planning	2-1
2.05	Resources	2-1
2.06	Information Resource Management Support Systems	2-2
2.07	Evaluation	2-2
2.08	Pharmacy Stock Control	2-2
2.09	Research	2-4
2.10	Operational	2-4
2.11	Committee	2-4
2.12	Professional	2-5
2.13	Occupational Safety and Health Responsibilities of the Service Chief	2-5

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19,1994

RESCISSIONS

The following material is rescinded:

Manuals

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

M-2, Part VII, Chapter 2, change 1 dated June 8, 1993

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

CHAPTER 2. ADMINISTRATION

2.01 POLICY

Pharmacy Service provides comprehensive pharmaceutical services to effect optimal quality patient care in the most therapeutically effective manner while efficiently and economically administering the total pharmacy program.

2.02 SCOPE

a. Provide for the pharmaceutical needs inherent in a dynamic health care delivery system, the total Pharmacy Service program must provide the administrative, professional/clinical, and distributive services necessary to effectively carry out the objectives of the program.

b. The components of comprehensive pharmaceutical services include, but are not limited to, the following:

(1) The development, evaluation, and communication of comprehensive information on pharmaceuticals and their use to the medical center staff, patients, and their families.

(2) The procurement, storage, distribution, and control of all pharmaceuticals used within the medical center.

(3) The monitoring, evaluation, and assurance of the quality of drug usage within the medical center.

c. The Chief, Pharmacy Service, will develop clinical pharmacy activities and ensure the development and management of comprehensive pharmaceutical services.

2.03 ORGANIZATION

Resources necessary to provide comprehensive pharmaceutical services will be under the direction, supervision, and control of the Chief, Pharmacy Service. The Pharmacy Service organizational chart and functional statements will reflect authorized manpower and resources. Organizational charts and functional statements will be reviewed periodically and revised as necessary.

2.04 PLANNING

Planning involves the daily activities of Pharmacy Service with short- and long-range objectives consistent with the objectives of the comprehensive pharmacy program and integrated with medical center goals and objectives. The Chief, Pharmacy Service, will be responsible for informing management of the resources required to meet these objectives.

2.05 RESOURCES

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

a. Appraisal. The Chief, Pharmacy Service, will apprise the medical center Director of resources needed (staffing, pharmaceuticals, budget, space, equipment, security, etc.), as outlined in Chapter 1, to carry out the mission of the medical center.

b. Funding. The chief pharmacist will be responsible for identifying, developing, and projecting budget requirements, and will maintain adequate records and reports to determine resource requirements.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

c. Every effort will be made to treat all Department of Veterans Affairs (VA) patients with the most effective therapeutic agents.

d. Funds will not be expended for purchase and administration of drugs classified ineffective by the Food and Drug Administration (FDA), including those subject to a notice of opportunity for hearing. The only exceptions are ineffective drugs utilized for investigational use in veteran patients.

2.06 INFORMATION RESOURCE MANAGEMENT SUPPORT SYSTEMS

Pharmacy Service will be provided appropriate computer support systems to automate those tasks requiring the repetitive or intricate processing of large amounts of data. These systems should include the centralized Decentralized Hospital Computer Program (DHCP) systems that facilitate the daily workload of pharmacy and the smaller micro-computer systems that are necessary to format data into more meaningful management reports for retrieval and dissemination of information. Word processing capabilities are also required as a part of the Management Support Systems. The computer support system must also have networking capabilities within the medical center, regions, and agency.

2.07 EVALUATION

The Chief, Pharmacy Service, will be responsible for submitting periodic (at least annually) evaluation reports of Pharmacy Service to management. The evaluation reports will identify those areas of service, consistent with established professional standards and necessary for the delivery of comprehensive pharmaceutical services, not being provided. This report will identify the resources necessary for implementing such services. The Pharmacy Service should be compliant with relevant standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the practice standards, guidelines, and technical assistance bulletins of American Society of Hospital Pharmacists (ASHP). When not in total compliance, the deficiencies should be noted and appropriate action taken.

2.08 PHARMACY STOCK CONTROL

a. Pharmacies will maintain routinely stocked items at levels consistent with anticipated usage. The Chief, Pharmacy Service, will explore mechanisms for utilization of technology and modern material management principles to increase the efficiency and effectiveness of inventory control and procurement. In cooperation with the Chief of Acquisition and Materiel Management, the chief pharmacist will ensure that pharmaceuticals are being purchased generically, where indicated, and from the most appropriate and economical mandatory source. Deviation from mandatory source for other than emergency needs will be in accordance with M-2, Part I, Chapter 3.

b. Drug stock will be properly shelved to ensure that the oldest stock will be used first. Storage practices should be consistent with established Occupational Safety and Health Administration (OSHA) and Fire Safety Regulations.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

c. All drugs subject to the Controlled Substances Act of 1970 (Pub. L. 91-513) must be completely and accurately inventoried on a biennial basis during the month of August, as indicated in 21 Code of Federal Regulations (CFR) 1304. Inventory of schedule II substances will be an exact count. Schedule III, IV, and V substances will be recorded to the closest 10th of a unit, e.g., Diazepam tablets 5mg, 500s--16.3. If the container

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

holds more than 1,000 dosage units, an exact count must be made if the container has been opened. The inventory will be recorded in a manner that permits easy verification by an inspecting official. The facility Director will designate an employee to verify the inventory of a representative number of items. The designated employee will not be a Pharmacy Service employee, nor an employee involved in taking the annual inventory. Records of the inventory will be retained in Pharmacy Service. Disposal will be in accordance with Veterans Health Administration (VHA) Records Control Schedule 10-1 and applicable FDA and Drug Enforcement Administration (DEA) regulations. Inventories of controlled substances will not be maintained in local A&MM (Acquisition and Materiel Management) warehouse space.

d. Pharmacy stock levels for drugs and supplies will be established. Special effort will be made to ensure that adequate levels are maintained.

e. The Chief, Pharmacy Service, will assure proper storage of pharmaceuticals to avoid loss or deterioration of drugs for which special storage facilities, such as refrigeration, are required. Proper storage facilities regarding safety and security will be in accordance with existing regulations. The Chief, Pharmacy Service and the Chief, A&MM Service, will cooperate in implementing provisions to account for the return or exchange of unserviceable drugs and other items with suppliers or manufacturers. To reduce the risk of medication errors, neuromuscular blocking agents will be stored in an inventory area apart from other injectable or intravenous agents.

f. At least once monthly, a Pharmacy Service employee will inspect all wards and clinic stocks of pharmaceuticals, removing outdated, deteriorated, or excessive stock. The pharmacy will ensure that ward and clinic pharmaceuticals are maintained in an economical and efficient manner under proper storage conditions. Appropriate records of such action will be maintained on VA Form 10-0053, Medication Inspection for Wards and Clinics.

g. All pharmaceuticals bearing expiration dates will be kept in current dating. They will not be dispensed or kept in ward, clinic, or pharmacy stock beyond the expiration date shown on the package. Stock will be rotated to ensure the shortest dated items will be used first. Pharmacies will develop an internal expiration system when repackaging pharmaceuticals from the original manufacturer's container. Unless otherwise specified, the expiration date shall be the last day of the month listed.

h. Safety Precautions

(1) Poisonous drugs and chemicals in pharmacies, wards, and clinics will be clearly labeled "poison," and will include such other necessary warnings as may be indicated. Externals and disinfectants will be stored separately from internal and injectable medication. Pharmacy Service will work closely with the appropriate safety personnel in the development, distribution, and maintenance of hazardous products listings and monographs.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

(2) A readily available supply of common antidotes will be maintained by Pharmacy Service in a convenient, readily accessible location in the medical center or clinic. Information on common antidotes and their uses will be currently maintained and kept conveniently available as will a poison control center telephone number.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19,1994

2.09 RESEARCH ACTIVITIES

Pharmacy Service should actively participate in pharmacy related and drug related research efforts. This may include involvement in one or all of the following:

- a. Pharmaceutical research with new drug dosage forms, drug preparations, and administration methods and systems.
- b. Clinical research of a therapeutic nature in the evaluation and comparison of drugs and drug treatment regimens.
- c. Behavioral and socioeconomic research dealing with compliance and cost benefit issues.
- d. Operational research in the evaluation of new and existing pharmacy practices and programs.

2.10 OPERATIONAL GUIDELINES

A policy and procedure manual will be developed and maintained by the Chief, Pharmacy Service, for each specific identifiable activity. The manual should be reviewed annually and updated when necessary. New employees to the Pharmacy Service should be oriented using the policy and procedures manual, as well as other Standard Operating Procedure (SOP) guidelines.

- a. To the extent consistent with VA regulations and policy, pharmaceuticals should be dispensed to community nursing homes in accordance with State nursing home regulations.
- b. Pharmacy Service will adhere to VA Regulations 501 through 584 and VHA manual M-1, Part I, Chapter 9, for release of information regarding beneficiaries. Information requests can be referred to Medical Administration Service for appropriate action.

2.11 COMMITTEE MEMBERSHIP

a. Active participation on professional and administrative committees is essential and consistent with the development and maintenance of quality pharmaceutical services. The Chief, Pharmacy Service, or designee, will be a voting member of the Pharmacy and Therapeutics Committee and it is strongly recommended that Pharmacy Service have representation on the following committees:

- (1) Clinical and/or Administrative Executive Board.
- (2) Resource Management.
- (3) Infection Control Committee.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

- (4) Quality Assurance Committee.
- (5) Research and Development Committee.
- (6) Drug Use Evaluation Committee.
- (7) Occupational Health and Safety Committee.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19,1994

(8) Nutritional Support Committee.

(9) Education Committee.

b. There may be other important committees not mentioned that are specific to individual medical centers. The chief pharmacist must review each committee's functions and determine how pharmacy is affected.

2.12 PROFESSIONAL ORGANIZATIONS

All employees should be encouraged to participate in the various professional organizations at the local, state, and national levels.

2.13 OCCUPATIONAL SAFETY AND HEALTH RESPONSIBILITIES OF THE SERVICE CHIEF

a. Provide employees safe working areas and conditions of employment.

b. Maintain a written occupational safety and health (OSH) policy and program which contains issues pertaining to the specific hazards of the worksite.

c. Conduct specialized training sessions to assure employees are adequately educated in specific job hazards and document the training in each employee's personnel file.

d. Maintain a list of OSH training provided to employees.

e. Authorize absence for treatment of job related injuries/illnesses sustained by employees.

f. Investigate job related accidents and hazardous conditions reported by employees. The accident investigation report shall be forwarded to the Facility Safety Official (FSO) within 10-days of the accident.

g. Initiate action for the correction of hazards.

h. Assign light duty to employees injured on the job, and coordinate the assignment with the employee health physician, the FSO, and personnel specialist.

i. Provide the Facility Industrial Hygienist (FIH) or FSO with a list of chemicals purchased. EXCEPTION: This requirement does not apply to drugs that are in solid final form for direct administration to the patient, cosmetics, foods, color additives, or ingredients in such products.

j. Provide the FIH or FSO with information on new chemicals procured.

k. Implement labeling and posting requirements for toxic substances or harmful physical agents.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994

l. Assure Material Safety Data Sheets (MSDS) are accessible to employees for all hazardous chemicals used, unless the FSO has granted an exception.

m. Assure that the purchase request for hazardous chemicals contains the words "HAZARDOUS: MSDS REQUIRED" on the description line of the request
EXCEPTION: If the FSO or FIH grants a waiver for a hazardous chemical, the words "HAZARDOUS: MSDS NOT REQUIRED" must be on the description line of the request.

January 19, 1994

M-2, Part VII
Chapter 2

M-2, Part VII
Chapter 2

January 19, 1994