

Department of Veterans Affairs
Veterans Health Services and
Research Administration
Washington, DC 20420

M-2, Part VII

March 28, 1991

1. Transmitted is a complete revision of the Department of Veterans Affairs, Veterans Health Services and Research Administration Manual M-2, "Clinical Affairs," Part VII, "Pharmacy Service."

2. The manual has been revised to incorporate all expired interim issues and circulars, as well as all changes to the manual since last published December 5, 1977.

3. Filing Instructions

Remove		pages
		Insert pages
i	through	10-2
		Cover through iii

1-1 through 9-3

4. **RESCISSIONS:** Manuals: M-2, Part VII, dated December 5, 1977, and all changes thereto. Interim Issues: II 10-75-2, II 10-79-11, II 10-80-53, and 10-80-58, and VHS&RA Circulars 10-78-204, 10-85-46, 10-85-97 and Supplements 1 and 2, 10-85-114, and 10-87-67.

James W. Holsinger, Jr., M.D.

Chief Medical Director

Distribution: **RPC: 1030**
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Department of
Veterans Affairs

Clinical Affairs
Pharmacy Service

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Veterans Health Services and Research Administration Manual M-2, "Clinical Affairs," Part VII, "Pharmacy Service," is published for the compliance of all concerned.

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RESCISSIONS

The following material is rescinded:

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a. **Manuals**

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M-2, part VII, dated December 5, 1977, and changes 1 through 8

b. **Interim Issues**

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CHAPTER 1. GENERAL REQUIREMENTS

1.01 GENERAL

Pharmacy Service, as an essential component of health care delivery in VA (Department of Veterans Affairs), is charged with the provision of patient oriented pharmaceutical services. The pharmacist's contribution is a thorough knowledge of drugs and their actions. Pharmacy Service programs encompass:

- a. **Administrative Services.** Responsible for planning, organizing and directing pharmacy programs. Provides administrative support to all sections of the pharmacy and to top management. Interacts with medical center management on all pharmacy concerns, including fiscal and quality of care itself.
- b. **Professional/Clinical Services.** Responsible for the provision of drug information for all who utilize, prescribe, dispense, and administer drugs.
- c. **Distributive Services.** Responsible for the provision of outpatient and inpatient pharmaceutical services and products. This includes procuring, dispensing, and maintaining proper records of all pharmaceuticals, including controlled substances and investigational drugs.
- d. **Specialty Pharmacy Services.** Includes those services not defined in subparagraphs a through c such as Radiopharmacy, Research Pharmacy, etc.

1.02 AVAILABILITY OF PHARMACY SERVICES

a. Each health care facility pharmacy (medical center, outpatient clinic, domiciliary, nursing home care unit, Drug Dependency Treatment Center, etc.) should be provided the appropriate staff, space, equipment, fixtures, and other resources to meet JCAHO (Joint Commission on Accreditation of Healthcare Organizations) and VA manual requirements necessary to provide quality and timely services for optimum patient care delivery.

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

(1) Where pharmacy services are not provided 24 hours a day, 7 days a week, the chief pharmacist will be responsible for developing and maintaining an on-call duty roster to meet the needs of medical center patients during off hours. Entrance to the pharmacy by other than pharmacy personnel will be permitted only in emergencies and with strict controls.

(2) Outpatient pharmacy hours should be sufficient to support normal clinic hours of operation. When not open for normal operation, back-up services must be provided for emergency prescription requests.

1.03 STAFFING

All pharmacies should be adequately staffed for the size and scope of services of the facility. All positions will be assigned to and under the supervision of the Chief, Pharmacy Service.

(1) **Professional/Clinical.** All pharmacies will be staffed with a Chief of Service, who is responsible for the overall operation of the service. In the Chief's absence, a licensed pharmacist will be designated to act as the Chief of Service. Other licensed pharmacists

will be provided for supervision and performance of all professional functions. Current licensure in a State, territory of the United States, or the District of Columbia, will be maintained by all licensed pharmacists. It is the responsibility of a pharmacist, whether seeking employment or already employed by VA, to inform the appropriate personnel if any license granted by a State, territory of the United States, or the District of Columbia has been suspended or revoked. The pharmacists shall immediately inform the appropriate VA personnel as to when the license was revoked/suspended and the reason(s) why. Verification of current licensure will be completed annually by the Chief, Personnel Service. The pharmacist's license and current renewal will also be displayed or readily available.

(2) **Technical.** All pharmacies should be adequately staffed by support personnel to assume many of the routine non-professional duties associated with the delivery of pharmacy services. Support personnel should be defined and properly classified. Duties performed by support personnel will be under the supervision of a pharmacist.

(3) **Administrative.** All pharmacies should be adequately staffed with administrative support personnel (secretary, clerk typist, receptionist, etc.) to perform those duties of a clerical nature and not of a professional or technical nature. In order to carry out the necessary administrative functions of the office of the Chief, a full-time secretary position should be provided the Chief of Pharmacy Service.

1.04 SECURITY

a. Physical security of the pharmacy will be in accordance with current security regulations as defined in VHS&RA (Veterans Health Services and Research Administration) Supplement, MP-1, Part I, Chapter 2, "Investigation, Security, and Law Enforcement Policy."

b. For internal security purposes, issuance of door keys, security cards or combinations to pharmacy personnel will be on a basis of need as determined by the Chief, Pharmacy Service. Strict accountability of security access must be maintained, and keys, cards, and combinations should be changed when employees with security access cease to be employed by Pharmacy Service. Security cards or combinations for controlled drug vaults and safes will likewise be limited to those individuals requiring access, and will be changed in accordance with VHS&RA Supplement, MP-1, part I, chapter 2.

c. Access doors to Pharmacy Service will be secured at all times, and access to pharmacy by non-pharmacy employees will be tightly controlled by the Chief Pharmacist or a supervisory designee.

d. Issuance of security cards and keys will be tightly controlled and kept on file in the pharmacy. Keys designated to the pharmacies are special keys, not mastered to the facility grandmaster, and replaceable only at the request of the Chief Pharmacist.

1.05 SPACE

In keeping with the mission of the VA facility, space should be provided for the administrative, professional/clinical, distributive, and other specialty pharmacy activities as outlined in the Office of Facilities Handbook H-08-9, Chapter 268, "Planning Criteria for VA Facilities."

1.06 EQUIPMENT

In keeping with the mission of the VA facility, necessary equipment will be provided in accordance with the Office of Facilities Handbook H-08-5, Chapter 268, "Equipment Guide List." Other equipment should be provided as required.

1.07 FIXTURES AND FURNITURE

In keeping with the mission of the VA facility, necessary fixtures and furniture will be provided in accordance with the Office of Facilities Handbook H-08-5, Chapter 268, "Equipment Guide List." Other fixtures and furniture should be provided as required.

1.08 MISCELLANEOUS

a. In order to make space, staff, and equipment allocations effective, other environmental standards will be provided.

b. Temperatures will be controlled by joint agreement between Pharmacy and Engineering Services. To avoid loss or deterioration of drugs, the installation and proper maintenance of air conditioning or related equipment will be made to ensure compliance with manufacturers' and official compendia recommendations.

c. Facilities required for the proper storage, preparation, venting, and other handling of hazardous (poisonous, flammable, carcinogenic) products will be provided.

d. Facilities required to provide an environment necessary to carry out aseptic techniques in the preparation of sterile products will be provided.

1.09 REQUEST FOR PHARMACEUTICALS

All pharmaceuticals, which include drugs, radiopharmaceuticals, non-prescription medications, medical and nutritional supplies for outpatient use, and investigational drugs approved by the FDA (Food and Drug Administration), will be ordered by, received, stored, and dispensed by Pharmacy Service in accordance with DEA (Drug Enforcement Administration) and FDA regulations governing drugs and pharmaceuticals.

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CHAPTER 3. INPATIENT SERVICES

3.01 GENERAL

The Pharmacy Service will be totally responsible for drug distribution. Pharmacy Service will provide services consistent with the maintenance of a high standard of medical care to the hospitalized patient. These services will provide adequate controls for the receipt, distribution, control, accountability, and quality assurance of medication. Appropriate policies and procedures will be established by the Chief of Pharmacy Service for all inpatient activities.

a. A readily retrievable, computerized, medication profile system will be established. The medical center computer system (DHCP (Decentralized Hospital Computer Program) or equivalent) will be utilized regardless of the medication distribution system in use.

b. The Pharmacy Service will be responsible for planned and systematic monitoring and evaluation of the quality and the appropriateness of medication usage. This program will be an integral part of the overall quality assurance programs of the medical center.

c. Adequate staffing and space, as defined by existing criteria, will be provided for inpatient medication distribution programs, professional/clinical programs, and administrative programs.

d. Medication brought into the medical center by patients will, upon admission of the patient, be turned in to the Pharmacy Service for appropriate disposition. Medication will not be stored in the clothing room or with personal property. In the event no family member is present, Medical Administration Service and nursing personnel will assist in the collection of the patient's medication. They will seal the medication, write the patient's name, ward location, specific instructions, if any, and forward the package to the Pharmacy for disposition. Medications purchased by the patient remain the patient's personal property. Upon discharge, the patient must be given the option of having the personal property returned.

e. Medication(s) brought into the medical center by the patient will not be used unless the treating practitioner makes the determination that its use is appropriate, VA (Department of Veterans Affairs) cannot timely obtain such medication through the regular or everyday procurement methods, VA Pharmacy Service identifies the medication, and the VA physician has given specific written orders to administer the medication(s). If authorized for use, the pharmacy will relabel and reissue them in accordance with the practitioner's instructions and standard labeling procedures required for inpatient dispensing.

f. All medication orders, whether oral, topical, parenteral, or other must be rewritten when the patients are transferred to and from designated specialty areas or services.

g. All modifications or discontinuances of medication orders must be written on Doctor's Orders (set), VA Form 10-1158, or other approved forms, and signed by the physician. **Erasures, strike-overs, and rewrites will not be accepted.**

h. A direct copy of all prescribers' medication orders will be transmitted to the pharmacy.

i. All medication samples must be controlled by Pharmacy Service.

3.02 MEDICATION MANAGEMENT SYSTEMS

a. **Unit Dose.** A unit dose drug distribution system, which permits identification of the drug up to the point of administration, is strongly recommended for use throughout the medical center.

(1) Orders will be dispensed for individual patients for up to a 24-hour period. In the case of nursing home care units or long-term facilities/wards, quantities in excess of a 24-hour supply may be issued.

(2) All medication orders will be reviewed by a pharmacist prior to the dispensing of the drug. In cases where this is not possible, the pharmacist will review the order within a 24-hour period of the time in which it was written.

(3) Medication will be delivered to wards and clinics at scheduled times and in suitable containers which fully identify the patient.

(4) Medication dosage schedules will be established and arrangements made for off-schedule dispensing of "stat" and change orders.

(5) Unused medications determined by Pharmacy Service to be suitable for reissue will be returned to pharmacy stock.

b. **Automatic Replenishment (Ward Stock).** The automatic replenishment drug distribution system is one in which medications are prepackaged in an amount or volume consistent with the needs of the using ward or clinic and which permits distribution by pharmacy personnel. Unit dose packaged medications may be utilized in lieu of bulk bottles.

(1) DHCP computer records indicating the ward or clinic, the item(s) provided, and the quantities provided will be used as the record of inventory accountability. Pharmacy personnel will maintain DHCP computer records and will utilize those records for inventory accountability.

(2) Stock levels consistent with the needs of the using ward or clinic will be established by pharmacy and ward/clinic personnel. All prepackaged units will contain the name of the medication, the strength, the lot number, and the expiration date. Appropriate prepackaging records as the VA Form 10-1362, Pharmacy Service Prepackaging Record, will be kept to ensure the identification of the manufacturer if necessary.

(3) Medication returned and determined by Pharmacy Service to be suitable for reissue will be returned to pharmacy stock.

3.03 INTRAVENOUS FLUIDS, ADMIXTURES, AND CHEMOTHERAPY

a. All parenteral fluids and medications are ordered on VA Form 10-1158 or other approved form. Included in the medication order are the medication and dosage, IV volume, desired flow rate, and the stop date. The notation "TKO" or "KVO" (to keep vein open) should be accompanied with the appropriate flow rate determined by the physician.

b. All medication prepared for cancer chemotherapy must be prepared in an appropriate area separate from routine item preparation. Such preparations of potentially hazardous medications must be prepared in a vertical flow hood, which meets

all current OSHA (Occupational Safety and Health Administration) and ASHP (American Society of Hospital Pharmacists) requirements.

c. It is the responsibility of the nurse to notify pharmacy of any changes to the patient's IV status.

(1) **Pharmacy Receipt of IV Order**

(a) A standard response time will be maintained by the IV Admixture Service in order to be effective and responsive to patients' needs. Initial doses should be delivered within 1-2 hours after receipt of the correct request. Subsequent doses will be provided prior to the scheduled administration intervals.

(b) Stat requests should be reserved for initial doses required in less than 1 hour after the order is written.

(2) **Preparation of IV Admixture**

(a) On receipt of the completed IV order, the pharmacist will review the order, check the dosage, and verify input of all necessary information into the medical center computer system. Assessment of problems, interactions, or incompatibilities are the responsibility of the verifying pharmacist.

(b) All parenteral products are prepared in a suitable laminar flow hood using aseptic technique. The pharmacy label is affixed to the container, the container checked and verified by a pharmacist, and delivered to the patient care area. The preparation will be discarded if there is any evidence of contamination, precipitate, or other physical or chemical incompatibility.

(c) Labels will contain the patient's name, identifier number, ward/medical center locations, date prepared, identity of each additive, diluent, volume, flow rate (if specified), special instructions (if specified), the initials of the preparer, and the expiration date. Use of abbreviations is discouraged.

(d) All orders and preparation will be checked by a pharmacist prior to dispensing and administering of the product. The following is the minimum requirements for controlled checking:

1. The prepared admixture is checked for accuracy and completeness. Particular attention is given to patient identity, identity of the drug additive amounts added as evidenced by the empty vials or ampules used, and solutions used. The pharmacist will then initial on the label.

2. On receipt, on or before handling and/or administration of any IV, the registered nurse will check the IV label against the physician's written order. If there is any discrepancy, the registered nurse will contact the pharmacist for correction or resolution of the discrepancy.

(3) **Delivery and Disposal of IV Solutions/Admixtures/Chemotherapeutic Products**

(a) The IV Admixture Service will maintain at the nursing unit a supply of ordered IV solution/admixtures consistent with administration schedules.

Parenteral solutions will be delivered to the areas of use by pharmacy personnel. Those admixtures requiring storage at reduced temperatures will be placed in the refrigerators designated by Nursing Service.

(b) Unless otherwise specified on the IV label, all unused IV admixtures are to be returned to the pharmacy within 24 hours after receipt. Pharmacy personnel will monitor and control the IV stock level in the nursing area.

(c) Hazardous products will be disposed of according to medical center policy and applicable local, state, and federal requirements.

3.04 RADIOPHARMACEUTICAL (WHERE APPLICABLE)

A radiopharmaceutical is a drug, intended for the diagnosis and/or therapy of disease, where a part of its constituent atoms are radioactive nuclides. It is a pharmaceutical and, as such, must conform to all legal, ethical, and professional handling requirements of other pharmaceuticals. It is also a radioactive drug and must conform to all legal and safety requirements established by Federal Regulations.

a. Nuclear Medicine Service or Pharmacy Service is responsible for the storage and the compounding of radiopharmaceuticals.

b. Appropriate credentials for all pharmacists involved in the preparation of radiopharmaceuticals are required.

c. Quality control will be in accordance with current Federal Regulations concerning radiopharmaceuticals and radioactive diagnostic agents. Records of all compounded and dispensed material will be kept according to current Federal Regulations.

d. Proper storage areas are required for the storage, preparation, and disposal of radiopharmaceuticals. The designated area will conform with OSHA standards. The Service Chief will annually review the safety precautions which have been implemented.

3.05 COMPOUNDING

Quality control of both the production and the product of bulk compounding will be in accordance with the regulations found in 21 CFR (Code of Federal Regulations) Part 133. Appropriate records will be maintained.

CHAPTER 4. OUTPATIENT SERVICES

4.01 GENERAL

a. The outpatient veteran population constitutes the largest segment of beneficiaries for whom VA (Department of Veterans Affairs) provides continuous health care. Significant numbers of outpatients require medications on a continuing basis. Pharmacy Service is the principal professional service actually involved in providing this day-to-day therapy.

b. The Chief, Pharmacy Service, will apprise management as to the resources needed to provide timely outpatient services and options available to enhance the services provided.

c. Pharmacists will interact creatively with the medical staff to formulate policies and procedures. These policies and procedures will effectively utilize the expertise of the pharmacist to evaluate medication therapy and assess patient's response.

d. Appropriate clinical privileges for clinical pharmacy interaction will be approved by medical center management.

4.02 THE PRESCRIPTION

a. Prescriptions may be written on the following approved forms:

- (1) VA Form 10-2577d, Prescription Form,
- (2) VA Form 10-1158, Doctor's Order Sheet (set), or the
- (3) Action Profile, which is generated by the DHCP (Decentralized Hospital computer Program).

b. Prior to dispatching these forms to pharmacy for dispensing, the following information will be completed in a legible manner:

- (1) Patient's full name
- (2) Social Security Number
- (3) Current address
- (4) VA facility address
- (5) Name of medication (generic preferred)
- (6) Dosage form
- (7) Strength (metric preferred)
- (8) Quantity

- (9) Specific directions ("as directed" or "prn" is not acceptable)
- (10) Refills, if indicated
- (11) DEA (Drug Enforcement Agency) number, if appropriate

The prescriber must then sign and date the prescription form. Only one medication may be written on VA Form 10-2577d, Prescription Form. The use of pre-signed prescription forms **is not authorized**

c. The quantity dispensed will not exceed a 30-day supply for usual prescriptions. Each prescription may have a maximum of five refills or 6 months of therapy. Exceptions to the 30-day limitation may be made if the local medical center develops a listing, by generic name, of "maintenance" medications approved by the local P&T (Pharmacy and Therapeutics) Committee. The P&T Committee will consider patient care needs and safety, as well as local resources, in establishing this list. No prescription will be filled for more than a 3 months supply of "maintenance" medication and refills may not exceed 6 months of therapy.

4.03 PATIENT ELIGIBILITY

a. Patient eligibility determines the extent to which benefits are provided. Patient eligibility may limit the quantities of medications certain patients may receive. Determining patient eligibility is a function of Medical Administration Service. Patient eligibility data should be available in the computer data base and be visible to the pharmacist for determining quantities of medication and/or length of therapy for which the patient is eligible.

b. Unless otherwise determined by the local P&T Committee, the following maximum allowable quantities are authorized:

(1) **AUTH. ABS-96 Hours.** Authorized Absence, not to Exceed 96 Hours (Non-Refillable).

(2) **AUTH. ABS+96 Hours.** Authorized Absence, not to Exceed 14 days (Non-Refillable).

c. **EMP (Employee).** Immediate needs to 72 hours for emergency treatment and treatment for minor ailments which interfere with the immediate ability to perform duty may be granted (Non-Refillable).

d. **HBHC (Hospital Based Home Care) 30 days (5 refills).** Patients who may be furnished HBHC following termination of VA authorized inpatient care will be furnished medications and medical supplies from the Pharmacy Service.

e. **REG. DISCH (Regular Discharge) 30 days (non-refillable).** A patient given a regular discharge may be furnished a supply of medications (not to exceed 30 days) sufficient to maintain the prescribed regimen of care until other arrangements can be made.

f. **NBC (Non-Bed Care) 30 days (refillable).** Patients under commitment and/or for whom the medical center is receiving an institutional award may be furnished NBC when inpatient care has progressed to a point where it is reasonable to anticipate that treatment may be concluded satisfactorily on a non-bed status.

g. **PBC (Pre-Bed Care) 30 days (one refill).** Certain nonservice-connected veterans may be furnished pre-hospital outpatient services. Patients in PBC status may receive examination and treatment (including medications and supplies) in preparation of hospital care.

h. A&A and/or HB (Aid and Attendance and/or Housebound) 30 days (5 refills).

(1) Any veteran in receipt of increased pension for additional compensation or allowance based on the need of regular aid and attendance or by reason of being permanently housebound, or who, but for the receipt of retired pay would be otherwise eligible, may be authorized needed outpatient treatment on a staff or fee-basis, for any medical condition, including medications and/or medical supplies.

(2) A&A veterans, as well as housebound veterans, who elect to obtain treatment at other than VA expense (which is not part of authorized VA hospital or outpatient care) are eligible to receive prescribed medications and medical supplies from a VA pharmacy.

i. CNH (Community Nursing Home) 30 days (5 refills). When it is specified in the nursing home agreement that certain services and supplies are not included in the per diem rate, i.e., medications and medical supplies, such services will be provided by the VA medical center which authorized the care in the community nursing home. Nursing homes having contracts with private pharmacies under which a complete medication monitoring and delivery system is furnished will be encouraged to provide the same service to veteran-patients.

j. OPT SC (Outpatient Treatment Service-Connected) 30 days (5 refills). Medications and medical supplies prescribed for treatment of veterans for service-connected or adjunct condition will be furnished by the VA medical center providing the care.

k. OPT NSC (Outpatient Treatment Nonservice-Connected) 30 days (5 refills). Patients in OPT NSC status will generally be furnished treatment at the appropriate VA medical center nearest their home. The medical center providing care on a staff basis will furnish the prescribed medications and authorized medical supplies.

l. OTHER FED (Other Federal) 30 days (5 refills). To include military retiree, active military, Canadian and Allied Forces. When properly authorized, inpatient and outpatient services may be furnished beneficiaries of other Federal agencies with whom the Secretary has approved agreements and to Canadian, British, and Allied beneficiaries. The current VA per diem rate, or per visit rate, includes drugs which are normally provided VA beneficiaries under the same circumstances.

m. OPC (Outpatient Care) 30 days (5 refills). Veterans who are eligible for hospital care and who do not otherwise have entitlement to outpatient care. Patients in outpatient care status may receive examination and treatment (including medications and supplies) to obviate the need for hospital care.

o. Other-30 days (no refills). Intended for use when medication is prescribed for dispensing at VA pharmacies to non-veterans under unusual circumstances for humanitarian or legal liability purposes.

4.04 GENERAL REQUIREMENTS

a. Prescriptions will be filed in a manner that facilitates retrieval when it is necessary to verify data in the computer data base. All non-current prescriptive documents should be disposed of in accordance with VHS&RA (Veterans Health Services and Research Administration) Records Control Schedule 10-1. Prescriptions for Controlled Substances will be filed as required in chapter 5, paragraph 5.06.

b. All commercially prepared dietary tube feedings and nutritional products prescribed for outpatients will be dispensed by Pharmacy Service on the receipt of a properly completed and authorized prescriptions.

c. Prescription refills for medications and supplies for recurring and continuing needs will be dispensed on the request of the veteran in accordance with the authorization of the prescriber and/or the patient's needs to last until the veteran's next scheduled clinic visit. Prescriptions will be refilled only on request. Prescriptions will not be automatically dispatched to veterans.

d. VA Form 10-2294b, Medication Request Form, will be generated by the computer system to provide a convenient method for the veteran to request refills of the veteran's medications and/or medical supplies.

e. General medical supplies for outpatient treatment and prosthetic medical supplies, determined to be expendable stock items required for outpatient care and treatment, will be dispensed on prescription. The pharmacist may dispense refills for expendable supplies upon receipt of requests from patients with continuing eligibility for a period not to exceed one year from the date of the last signed order. Expendable stock items may include catheters, colostomy or ileostomy sets and supplies; plastic or rubber gloves, skin preparation and powders for orthotic and prosthetic appliance wearers, urinals, leg or canister type, urinary drainage supplies, incontinence supplies, etc. Non-expendable medical equipment such as wheelchairs, cushions, hospital beds, and related bedside equipment, commode chairs, invalid lifts, canes or crutches, etc., will not be included. The inventory volume, scope, and diversity of items will be standardized in accordance with the requirements of each facility.

f. Prescriptions written by one VA facility for dispensing by another VA facility should be discouraged. The treating facility should provide all prescribed medications. This does not apply to prescriptions written at a physically separated department of the same facility. Any loan or transfer of medications, medical supplies, etc., to other agencies or VA activities will be accomplished by the Chief, A&MM (Acquisition & Materiel Management) Service. In emergency situations, Pharmacy Service is authorized to borrow or loan to any other medical facility. Appropriate records of such transactions will be maintained.

g. Prescription medications or medical supplies dispensed by mail delivery will be securely packaged and properly addressed. Upon notification that mailed medications were not received, the veteran's data base in the computer will be appropriately annotated. In the event of a recurring loss, the registered/certified mail procedure for all prescriptions will be instituted. When appropriate, the patient's physician will be notified.

h. VA pharmacies are authorized to fill and mail prescriptions for controlled substances (Schedule II, III, IV, and V). The use of registered mail is not required.

4.05 PATIENT CONSULTATION

In order to provide quality medical care in a cost-effective manner, it is necessary that the patient comply with an appropriate medication regimen; therefore, it is mandatory that the pharmacist provide patient consultative services.

4.06 SUPPLEMENTAL PHARMACY SERVICE

a. Every effort will be made to utilize VA pharmacies for prescription services. When appropriate, arrangements will be made for emergency prescription services through pharmacies in a community within a clinic of jurisdiction area. These arrangements will be made on a selective, individual patient basis, after determination of the type and recurring nature of the prescription. Fee-basis physicians will be made aware of VA policies listed in paragraph 4.07b. Any pharmacy licensed by a State, territory of the United States, or District of Columbia is eligible to accept and fill prescriptions for VA patients, as may be required, in accordance with instructions issued by VA.

b. Eligible veterans in identification card status will be reimbursed, based on acquisition cost of an acceptable generic drug plus a VA determined dispensing fee, for prescribed medications purchased in emergencies (as defined by the clinic of justification).

c. When there is a reasonable doubt about the relationship of the prescribed medications in relation to the disability(ies) listed on the card, the participating pharmacist will contact the prescribing fee-basis physician for verification. If the prescribing physician verifies that the medication is for a condition listed, the participating pharmacist will annotate the prescription to indicate that verification was made and payment will be approved by the VA facility of jurisdiction. When VA Pharmacy Service and the reviewing VA physician concur that medication was not appropriate for the condition under care, and when agreement cannot be reached with the fee-basis physician, appropriate notification will be made to the participating pharmacy that payment will not be approved for additional prescriptions or refills of the medication in question. It is in the best interest of good patient care that all fee prescriptions be maintained in the patient's computer data base in the VA Pharmacy.

4.07 UTILIZATION OF VA PHARMACIES

a. Facility Pharmacies

(1) VA facility pharmacies will be used to fill staff prescriptions for drugs and supplies for authorized patients.

(2) Prescriptions and refill requests received through the mail will be processed and dispatched within 2 working days.

(a) On the first workday of each week, the Chief, Pharmacy Service, will review the outpatient mailout operation for timeliness of service. When a review indicates that a backlog of more than 7 calendar days exists, a report (to include date of report, period covered by report, date oldest prescription request received in Pharmacy and still unfilled, number of unfilled prescriptions more than 7 calendar days old and unusual specific circumstances causing the backlog) will immediately be submitted to the facility Director, with recommendations of appropriate actions to correct the backlog.

(b) When reports are made for more than 4 consecutive weeks to the facility Director, the Director will submit a report to the appropriate Regional Director (13_/141A8), VA Central Office, citing deficiencies, unusual circumstances involved, and corrective action taken.

(3) Drugs and supplies will be provided to eligible veterans on prescriptions completed by VA prescribers who are licensed to practice their profession and prescribe drugs in a State, territory, or possession of the United States, District of Columbia, or the Commonwealth of Puerto Rico.

b. Pharmacies in Clinics of Jurisdiction for Fee-Basis Care

(1) In addition to dispensing prescriptions written by staff in accordance with subparagraph a, pharmacies in clinics of jurisdiction for fee-basis care will be used to fill authorized fee-basis prescriptions (in accordance with applicable public laws and VA regulations and policy) to the extent practical and consistent with the needs and best interest of patients and VA.

(2) VHS&RA has established a formal goal that clinics of jurisdiction will fill at least 95 percent of the fee-basis prescriptions in VA pharmacies. VA Central Office officials will routinely monitor reports to determine compliance with this goal. If appropriate, VA Central Office officials will discuss with the officials of clinics not meeting the goal the types of actions necessary to reduce the number of non-emergency prescriptions being filled by private pharmacies.

(3) Authorized prescriptions received from patients or their fee-basis physician will be filled promptly and returned to the patient without delay. Local procurement of drugs for filling fee-basis prescriptions will be expedited for those items not in stock when the prescription is received. A&MM Service will make such arrangements for procurement of drugs not in stock so that the prescription can be dispatched within 2 working days after receipt of the prescription. Only medications on the local medical center's formulary will be used to fill fee-basis prescriptions. Fee-basis prescriptions will not be unduly delayed to determine eligibility.

(4) When oxygen is prescribed, an authorization will be issued to an appropriate supplier for direct delivery to a veteran in accordance with local facility policy.

(5) Prescriptions may be limited to a 30-day supply of medication and up to 5 refills may be authorized. Pharmacy Service will have access to all available eligibility information contained in the DCHP system for which a veteran is entitled to receive drugs and medicine. This will assist Pharmacy Service in determining that the medication is appropriate for the condition under care. Questions involving dosage, contraindications, synergism, and other professional matters will be discussed by the pharmacist with the Clinic Director, Associate Chief of Staff for Ambulatory Care, or physician/designee and, when indicated, resolved with the fee-basis prescriber by the VA physician or VA pharmacist as determined appropriate.

CHAPTER 5. CONTROLLED SUBSTANCES (PHARMACY STOCK)

5.01 GENERAL

a. These substances will consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR (Code of Federal Regulations) Part 1300:

- (1) Schedule II drugs are found in 21 CFR 1308.12,
- (2) Schedule III drugs are found in 21 CFR 1308.13,
- (3) Schedule IV drugs are found in 21 CFR 1308.14, and
- (4) Schedule V drugs are found in 21 CFR 1308.15.

b. These substances will be inventoried according to DEA (Drug Enforcement Administration) regulations. The controlled substances inventory record must be a separate listing.

c. Prescriptions and the completed Schedule II, VA Form 10-2320 Schedule III Narcotics Register, and VA Form 10-2321 Controlled Substance Order will be retained and securely stored. Disposal will be only in accordance with VHS&RA (Veterans Health Services and Research Administration) Records Control Schedule 10-1 (*in no event less than 2 years, as required by DEA regulations*).

d. All prescriptions for controlled substances will be dated as of, and signed on, the day when issued and will bear the full name and address of the patient, and the name, address, and DEA registration number of the practitioner. Prescriptions should not be filled if they are more than seven days old when presented.

e. An intern, resident, or foreign-trained physician, physician, or dentist on the staff of a VA (Department of Veterans Affairs) facility exempted from registration will include on all prescriptions issued the registration number of the VA facility and the special internal code number assigned by the VA facility in lieu of the registration number of the practitioner required by law (21 CFR 1306.05b). Each written prescription will have the name of the physician stamped, typed, or hand printed on it, as well as the signature of the physician.

f. The label of any drug listed as a "Controlled Substance" in Schedule II, III, IV, or V of the Controlled Substances Act will, when dispensed to or for a patient, contain the following warning: *"CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."*

g. All prescriptions for controlled substances will be stamped with the letter "C," in red ink, not less than 1 inch high, in the lower right corner, in accordance with 21 CFR 1304.4.

h. The medical center registration covers the entire institution provided the institution is at one location. Practitioners within the medical center are

exempt from registration; however, they will be assigned an internal code number. The exemption permits medical center personnel to carry out the functions of the medical center with respect to controlled substances without being personally registered. Pharmacists do not need a separate registration.

i. More stringent controls will be developed at local facility if deemed necessary by the Chief, Pharmacy Service.

5.02 ORDERING CONTROLLED SUBSTANCES

a. Schedule II Substances

(1) Pharmacy stock requirements of Schedule II substances will be ordered separately from non-controlled substances on VA Form 90-2138, Orders for Supplies or Services, or VA Form 90-2237, Request, Turn-in and Receipt for Property or Services. When separate requests are submitted on VA Form 90-2237, a letter "C" will be included in the top left margin to identify the items as controlled substances to facilitate auditing records by an inspector.

(2) Alternate methods of ordering Schedule II substances may be developed utilizing computerized systems as long as they comply with 21 CFR Part 1300.

b. Schedule III, IV, and V Substances

(1) Pharmacy stock requirements for Schedule III, IV, and V substances will be ordered from A&MM (Acquisition and Materiel Management) Service in accordance with current supply procedures.

(2) Computerized systems may be utilized to facilitate the ordering process.

5.03 RECEIVING AND STORING CONTROLLED SUBSTANCES

a. Receiving Schedule II Substances

(1) On receipt of Schedule II substances in the pharmacy, the responsible pharmacy designee will check receipts with the items and quantities appearing on the original issue list which lists only these substances. Discrepancies will be reconciled with the Chief of A&MM Service, or a designee, before supplies are accepted by the pharmacy.

(2) Appropriate entries will be made in computerized systems.

b. Receiving Schedule III, IV, and V Substances

On delivery from supply, the responsible pharmacy employee will check receipts for items issued for accuracy before signing and dating the original and pharmacy copy of the receiving document. Discrepancies will be reconciled with the Chief, A&MM Service, or designee, before supplies are accepted by the pharmacy.

c. Storing Schedule II, III, IV, and V Substances

(1) All controlled substances will be secured as outlined in paragraph 1.04.

(2) Combinations to medication safes or vaults and necessary keys will be controlled and distributed by the Chief, Pharmacy Service.

a. Schedule II Substances

(1) Unit Dose

- (a) Orders for Schedule II substances will be written by the physician on VA Form 10-1158 Doctor's Orders (set), or another approved form.
- (b) Schedule II substances may be dispensed for a period not to exceed 72 hours for individual patients (VHS&RA Manual M-2, part I, chapter 2).
- (c) Orders for Schedule II substances will be serially numbered with appropriate entries made on appropriate inventory records as the the Controlled Substance Administration Record, VA Form 10-2638, VA Form 10-2320, or an alternate computer generated entry.
- (d) Orders will be filed in a readily retrievable patient's medication profile or maintained through computer entry.
- (e) Each dose will be identified by name, form and strength, control number, and expiration date.
- (f) Schedule II substances for each patient will be delivered and dispensed at scheduled times, in a suitable container which identifies each patient by name. The container will be stored in a double locked cart.
- (g) Authorized nursing personnel will sign for Schedule II substance delivery.
- (h) Posting of all unused doses will be made by Pharmacy Service.
- (i) All orders for Schedule II substances to be administered to patients from unit dose or ward stock will be written for periods not to exceed 72 hours or less. When requested by the attending physician, exceptions not to exceed 14 days may be approved by the Chief of Staff to care for terminal illness and specific cases of nursing home residents. Stop order procedures for controlled substances will be in compliance with JCAHO (Joint Commission on Accreditation of Healthcare Organizations) recommendations and VHS&RA Manual M-2, part I, chapter 2.

(2) **Automatic Replenishment**

- (a) Appropriate levels consistent with the needs of the using ward or clinic will be established.
- (b) A supply of Schedule II substances will be issued to wards and clinics by an authorized pharmacy employee. An appropriate record will be made and maintained in the pharmacy of each item issued.
- (c) On reaching each ward and clinic, the authorized pharmacy employee, in the presence of the authorized nursing personnel, will note the balance on hand from VA Form 10-2638, or other approved form(s), and replenish enough of each item to reach established levels.
- (d) On the first unused line of VA Form 10-2638, the same serial number as on VA Form 10-2321 will be entered in "Name of Patient" column. The amount replenished will be indicated in the "Dose" column. This amount will be added to the amount indicated in the "Balance" column of the line above. The

authorized nursing personnel and the pharmacy employee will both sign in the "Administered By" column.

(e) Pharmacy Service will prepare a VA Form 10-2321 for each item replenished. VA Form 10-2321 will indicate the name, ward or clinic, strength, and amount of drug

replenished. Forms will be in ink or typewritten and serially numbered. The authorized nursing personnel will sign for controlled substances.

(f) VA Form 10-2638 for each item will be numerically numbered in a continual sequence. When a form is completed, the pharmacy employee will prepare a new form with the last balance of the completed form carried over to the beginning of new form.

(g) On return to the pharmacy, the issuing pharmacy employee will "tally" the amounts issued against the amounts replenished (using VA Form 10-2321 returned by the pharmacy employee). Remaining items will be returned to stock. Appropriate entries will be made on VA Form(s) 10-2320.

(h) A list of ward and clinic issues will be maintained by the pharmacy indicating series number, date, and amounts issued to each ward and clinic.

(i) Completed VA Form 10-2638 may be retained on the ward or clinic in separate folders, or separate sections if one binder is used, until picked up by authorized personnel. Each completed VA Form 10-2638 returned will be reviewed by a pharmacy employee prior to filing, for arithmetic, losses, or unusual waste. Discrepancies will be handled as in paragraph 5.07e.

(j) A random check of VA Forms 10-2638 entries against patient's charts will be made by the Controlled Substances Inspecting Official.

(k) Schedule II substances returned from wards and clinics and determined by Pharmacy Service to be suitable for reissue will be returned to stock. Appropriate entries will be made on VA Form 10-2320 and VA Form 10-2638.

(l) Computerized Automatic Replenishment Systems may be utilized as long as they comply with 21 CFR Part 1300.

(m) Stop order procedures will follow the policy outlined in 5.04a.(1)(i).

(3) Clinic or Ward Stock

(a) Schedule II substances will be dispensed on VA Form 10-2321, prepared in duplicate. Orders will be limited to one package per item per form. Forms will be completed in ink or typewritten, and original only will be signed by a physician, dentist, or registered nurse. The duplicate copy will be marked "duplicate" and retained on the ward. The duplicate will be checked for verification at the time of delivery.

(b) Orders for Schedule II substances will be filled by an authorized pharmacy employee. Unit dose packaged products, when available, will be used for all dosage forms.

(c) VA Form 10-2321 will be serially numbered, dated, and signed.

(d) VA Form 10-2638 will accompany each container issued.

(e) A serial number corresponding to the number assigned the order on VA Form 10-2321 will be placed in the appropriate space on VA Form 10-2638.

(f) Pharmacy Service will maintain a list of wards and clinics indicating serial numbers of all VA Form 10-2638 issued during the preceding months, as well as those carried over from previous inspections. The list will include the name, strength, and amount of the drug

issued. This list may be kept manually or through a computerized system.

(g) Schedule II substances will be dispensed and delivered by the authorized pharmacy employee for delivery to wards and clinics. A temporary record will be maintained in pharmacy until employee returns with the signed VA Form 10-2321.

(h) On receipt of Schedule II substances and the accompanying record forms, the authorized employee(s) making delivery to the ward or clinic will:

1. Check receipts for accuracy with the items and quantity appearing on VA Form 10-2321.

2. Check the serial number of VA Form 10-2638 against the serial number of VA Form 10-2321.

3. Sign and date receipt on VA Form 10-2321. On return to the pharmacy, the authorized employee will return the signed VA Form 10-2321 and the records will be cleared.

(i) When Schedule II substances are delivered to the ward by the authorized employee(s), the nurse will check the drugs and record forms for accuracy and sign for receipt of VA Forms 10-2321. If discrepancies exist between the amount ordered and the amount received, the nurse will check with the designated pharmacy employee concerning the amount issued. If the discrepancy is not resolved, reports will be made immediately, through the responsible supervisors, to the Medical Center or Clinic Director for investigation and necessary action.

(j) Completed VA Forms 10-2638 returned from wards and clinics will be cancelled from the list and filed in separate folders, or separate sections if one binder is used. Each completed VA Form 10-2638 returned will be reviewed by a designated pharmacy employee prior to filing for arithmetic, losses, or unusual waste. Discrepancies will be referred as soon as practicable, through the responsible supervisor, to the Controlled Substances Inspecting Official, medical center or clinic Director for investigation and necessary action.

(k) A random check of VA Form 10-2638 entries against patients' charts will be made by the Controlled Substances Inspecting Official.

(l) Stop order procedures will follow the policy outlined in 5.04a(1)(i).

(m) A computerized system may be utilized as long as it complies with Federal Regulations and Central Office policy.

(4) **Compounded Schedule II Substances**

(a) Compounded Schedule II substances, intravenous or oral, etc., will be ordered on a Prescription Form, VA Form 10-2577d, and on Doctor's Orders (set), VA Form 10-1158.

(b) The order will be handled according to Section 5.04a(1)(b)-(g).

(c) Stop order procedures will be in compliance with JCAHO and VA Central Office policy.

(d) When Schedule II substances are used in bulk compounding stock preparations for later issue, the pharmacist will complete VA Form 10-2321, which will serve as a bulk

compounding record, indicating the name and quantity of the Schedule II substances used, and the name and quantity of preparation to be compounded. The form will be prepared in ink or typewritten, serially numbered, dated, signed by the pharmacist issuing the Schedule II substances, and initialed by the individual using the substances. Appropriate entries will be made on VA Form 10-2320.

(5) **Outpatient Services**

(a) Schedule II substances for individual patients will be ordered on properly completed VA Form 10-2577d, VA Form 10-1158, or another approved form.

(b) The prescription will be serially numbered, dated, and cancelled by the pharmacist's signature across the face of the form.

(c) Partial dispensing of Schedule II substances may be done as long as it is in compliance with 21 CFR 1306.13 and VA Central Office policy.

(d) Schedule II substances prescriptions must be filed in accordance with paragraph 5.06.

(e) Prescriptions written for Schedule II substances filled by VA pharmacies may be mailed in compliance with 21 CFR Part 1300, VA Central Office policy, and postal regulations.

b. **Schedule III-V Substances**

(1) **Unit Dose**

(a) Orders for Schedule III-V substances will be written by the authorized prescriber on VA Form 10-1158 or other approved forms.

(b) The quantity dispensed shall not exceed 72 hours for individual patients.

(c) Each dose will be identified by name, form and strength, control number, and expiration date.

(d) Schedule III narcotic substances may be dispensed for a period not to exceed 72 hours for individual patients (VHS&RA Manual M-2, part I.). Specific requirements not to exceed 72 hours apply only to Schedule III narcotic substances and exceptions apply. Schedule III-V non-narcotic controlled substances will follow the stop order procedure established by the medical center P&T (Pharmacy and Therapeutics) Committee.

(2) **Automatic Replenishment or Ward Stock**

(a) Schedule III-V substances will be ordered by pharmacy or ward personnel on VA Form 10-2566-1 Doctor's Orders (sheet), or through the computerized automatic replenishment program. When the controlled substance is delivered to the ward or clinic, a physician, dentist, registered nurse, or licensed practical nurse will sign for receipt of the substance.

(b) Usage rate records of Schedule III-V substances dispensed to wards and clinics will be maintained by the pharmacy and will include:

1. Ward or clinic receiving the issue.

2. Name, strength, quantity, and date the substance was issued.

3. Tabulation of monthly totals by wards and clinics of each drug issued.

(c) Schedule III-V substances returned from wards and clinics and determined by the pharmacist to be suitable for reissue will be returned to stock. A record of these returns will be on VA Form 10-2566-1 listing these drugs only.

(3) Outpatient Services

(a) Schedule III-V substances will be ordered by an authorized prescriber on properly completed VA Form 10-2577d, VA Form 10-1158, or other approved form.

(b) The prescription will be serially numbered, dated, and filed in accordance with paragraph 5.04.

(c) Partial filling of Schedule III, IV, and V substances is permissible, provided that it is in compliance with 21 CFR 1306.23.

5.05 METHADONE MAINTENANCE TREATMENT PROGRAM

Facilities must be licensed for this program. See FDA (Food and Drug Administration) regulations, 21 CFR 310.305.

a. **Ordering and Storage**

(1) Pharmacy stock requirements of methadone for a maintenance program will be ordered separately from other Schedule II substances on VA Form 90-2138 or VA Form 90-2237.

(2) Only oral, liquid form will be utilized for a treatment program.

(3) Methadone for the maintenance treatment program will be stored according to Federal Regulations and Central Office policy.

b. **Dispensing**

(1) Methadone for maintenance treatment will be dispensed on receipt of VA Form 10-2577d, VA Form 10-1158, or other approved form, written by a physician who has submitted a FDA Form FD-2633 Medical Responsibility Statement for Use of Methadone in a Treatment Program.

(2) Methadone will be packaged and dispensed in a single dose form conforming to "Public Law 91-601, Poison Prevention Packaging Act of 1970," and subsequent amendments.

(3) Each take home dose will be dispensed in a child resistant container and will be labeled with the treatment center's name, address, telephone number, and physician's name.

5.06 RECORDS AND FORMS

a. **Schedule II Substances**

(1) Receiving documents for all Schedule II substances must be maintained separately from all other records.

(2) Completed VA Form 10-2321 for ward stock orders will be filed separately in a numerical file.

(3) Completed VA Form 10-2577d, for Schedule II substances dispensed to outpatients will be filed separately in a numerical file or according to 21 CFR 1304.04.

(4) Schedule II substances will be serially numbered in a sequence used only for these substances.

(5) Schedule II substances entered into the DHCP (Decentralized Hospital Computer Program) Pharmacy software package will be coded in the "DEA Special Handling" fields designated 2A, and 2L.

b. **Schedule III-V Substances**

(1) Schedule III-V substances prescriptions will be filed in compliance with 21 CFR 1304.04.

(2) Schedule III-V substances entered into the DHCP Pharmacy software package will be coded in the "DEA, Special Handling" fields, designated 3 through 5 (L, A, and C).

5.07 INSPECTION AND TRANSFER OF RESPONSIBILITY

a. **Inspection in Pharmacy.** Monthly inventory and inspection of pharmacy stock and records will be made in the presence of the Chief, Pharmacy Service, or a designee. The inspecting official will date and sign VA Form 10-2320 for each drug or preparation at the time of the inspection, certifying the accuracy of the records.

b. **Transfer of Responsibility.** In the temporary absence of the Chief, Pharmacy Service, the facility pharmacist designated as Acting Chief will automatically assume responsibility for security and control of controlled substances. On permanent change of facility or when a rotating or relief pharmacist is temporarily in charge of Pharmacy Service, a complete inventory will be conducted. This inventory will be conducted by the incoming Chief or pharmacist temporarily in charge, jointly with the appointed facility inspecting official. A record of the inventory will be made on VA Form 10-2320 for each drug inventoried and will be signed by the outgoing and incoming Chief (or Acting Chief) and the facility inspecting official. Any discrepancy will be made a matter of record and, if indicated, an investigation made to determine the cause of the discrepancy.

c. The Chief, Pharmacy Service, or a designee, will submit monthly, or as otherwise directed, to the appointed responsible inspecting official(s), a complete list by wards and clinics, of the serial and sheet numbers of VA Form 10-2638 which will be available on the Nursing units. This list will be used by the inspecting official in the monthly check of ward and clinic Schedule II substance stocks and records to confirm that all records and stocks are available for inspection. The inactive VA Form 10-2638 returned to the pharmacy since the last inspection will also be available to the inspecting

official. In addition, all automatic replenishment records for Schedule II substances will be provided.

d. **Inspection of Wards and Clinics**

(1) The inventory and inspection of ward and clinic Schedule II substances and records will be made in the presence of head nurses or in their absence, the nurse in charge.

(2) The inspecting official will certify by memorandum to the Director, the accuracy of the records and inventory of Schedule II substances in the units which have been inspected. Wards and clinics will be specified. The lists used by the inspecting official in conducting the inspection will be returned promptly to the pharmacy.

e. Procedure in Case of Loss

(1) In cases of accidental loss, breakage, or destruction of small quantities of Schedule II-V substances (such as single doses), the appropriate Schedule II substances record will be balanced and a brief explanation of the circumstances entered on VA Form 10-2320 or Form 10-2638, as indicated. Entries and explanation will be signed by the person responsible for the loss or breakage and called to the attention of their immediate supervisor at the earliest opportunity. The immediate supervisor will countersign VA Form 10-2638 and VA Form 10-2320. If the explanation is not considered satisfactory, the incident will be reported to the Director for investigation and necessary action to prevent recurrence.

(2) In cases of recurring shortages, loss of significant quantities of Schedule II-V substances (several doses), or if there is indication of theft, a report will be made to the Director and a Report of Theft or Loss of Controlled Substances, DEA Form 106, shall be completed in accordance with 21 CFR 1301.74. Losses discovered during monthly inspections will be reported to the Director by the inspecting official.

(3) In case of suspected theft by substitution, reports will be made to the Director, who will direct that the suspected material be analyzed by a qualified analyst. Adjustment will be made in the appropriate record by the Director or a designee, for quantities used in the testing procedure. If substitution is confirmed, an immediate investigation will be conducted.

(4) On completion of the investigation, quantities of Schedule II-V substances lost for analysis or otherwise removed from stock in connection with the investigation involved will be dropped from the record with an appropriate written explanation opposite the entry. Records will be balanced and all entries and explanatory remarks signed by the Director or a designee.

5.08 DISPOSITION OF EXPIRED OR EXCESS Schedule II

a. Excess Schedule II substances in wards and clinics will be returned to Pharmacy Service for redistribution or turn-in and items determined unsuitable for reissue by Pharmacy Service, will be accepted in the pharmacy for storage purposes only, prior to acceptance by the Chief, A&MM Service, for disposal. The following procedure will be used:

(1) The nurse will prepare, in duplicate, VA Form 10-2321 for each Schedule II substance turned in for disposition. The form will be prepared in ink or typewritten and will be clearly marked "Turn-in Slip." The following information will be included:

(a) Designation of ward or clinic.

(b) Date.

(c) "Believed" or "purported" identity of the Schedule II substances.

(d) Size, strength, etc., of the Schedule II substances.

(e) Quantity.

(f) Signature of nurse.

(2) The nurse will take to the pharmacy:

(a) The Schedule II substance to be returned.

(b) VA Form 10-2321 prepared in duplicate in accordance with subparagraph 5.08a(1).

(c) VA Form 10-2638 for the Schedule II substances being returned.

(d) The authorized pharmacy employee will check the alleged Schedule II substances in the presence of the nurse and will place each item returned in a separate envelope. The date, name of substance "believed" or "purported" to be returned in, and quantity will be written in ink or typewritten on each envelope. Each envelope will be dated, sealed, and signed across the seal by the authorized pharmacy employee and the nurse. The closure of the envelope will be reinforced with clear cellophane tape covering the signatures. The sealed drugs will be stored in the pharmacy safe or vault apart from other drugs or current stocks.

(3) The authorized pharmacy employee will date and sign receipt on the original and duplicate of VA Form 10-2321 and return the original to the nurse as a receipt for the drug and VA Form 10-2638. The duplicate will be retained in the pharmacy in an "Excess Schedule II Substance File," which will be established for this purpose.

(4) VA Form 10-2638 will be used to indicate the following:

(a) Date in the "Date" column.

(b) "Return to Pharmacy for disposition" in "Name of Patient" column.

(c) Signature of nurse and inspecting official in "Administered By" column.

(d) Entries will be made on the line following the last entry for administration of the substances.

(e) Form will be cancelled by drawing a diagonal line across the remainder of the sheet.

b. Excess or unusable Schedule II substances will be removed from pharmacy's stock at the time of the regular monthly inspection. The date, reason, and amount removed from pharmacy stock will be indicated on VA Form 10-2320. The form will be signed by the chief pharmacist, or a designee, and the inspecting official. Each item removed from stock will be placed in an envelope as described in paragraph 5.08a(2)(d), but will be signed by the chief pharmacist or a designee and the inspecting official.

c. Schedule II substances returned by the postal service as undeliverable and those not picked up by patients at the pharmacy window will be returned to pharmacy stock if determined to be suitable for reissue. VA Form 10-2320 will show date, prescription number, patient's name, quantity returned to stock, and inventory adjustment. A supervisory pharmacist and a staff pharmacist will sign on the next unused line as witnesses to the transaction. The patient's prescription will be marked "returned to pharmacy stock," dated, and signed by the supervisory pharmacist and staff pharmacist.

d. Schedule II substances returned by patients and family members and those returned by the postal service and determined not suitable for reissue will be placed in an envelope, one item per envelope as described in subparagraph 5.08a(2)(d), but will be signed by a supervisory pharmacist and a staff pharmacist.

e. Each envelope will be given a consecutive serial number when prepared for storage of the Schedule II substance. Each Schedule II substance will be entered on DEA Form 41 Registrants Inventory of Drug Surrender, along with the corresponding serial envelope number. The number of containers, contents, and units will also be completed.

f. A copy of DEA Form 41 will be attached to VA Form 90-2237 as a "turn-in." VA Form 90-2237 will state: *"See Attached List of Schedule II Substances for Turn-in."*

g. All expired or excess Schedule II substances will be stored in the pharmacy vault or safe.

h. At appropriate intervals, these substances will be turned in to the Chief, A&MM Service, for disposition. The disposition will be witnessed and attested to by the Chief, A&MM Service or designee, the Chief, Pharmacy Service, or designee, and an inspecting official.

i. When it is necessary to "waste" part of a Schedule II substance unit on the ward or clinic, two entries will be made.

(1) The first entry will be the dose given (one-half ampule, 25 mg, etc.).

(2) The second entry will be the amount wasted (one-half ampule wasted, 25 mg wasted, etc.).

(3) A registered nurse may waste a partial dose of a Schedule II substance. The wasting of the dose must be witnessed by an authorized nursing employee. The amount "wasted" will be disposed of in an appropriate manner.

5.09 Schedule II SUBSTANCES IN RESEARCH AREAS

a. Procurement

(1) All Schedule II substances for use in research (animal or human) will be ordered on VA Form 90-2237 through A&MM Service.

(2) On receipt, A&MM Service will issue the drug to Pharmacy Service. The drugs will be charged to the appropriate research cost control point. Pharmacy Service will then reissue the drug to the appropriate research area.

b. Issue

Issuance of Schedule II substances to Research Areas will be in accordance with the general provisions for dispensing controlled substances outlined in paragraph 5.04. Persons authorized to receive controlled substances will be

designated by the medical center Director on the advice of the Associate Chief of Staff for Research and Development or the Chief of Staff.

c. **Control**

- (1) One VA Form 10-2638 will accompany each container issued.

(2) Authorized employee(s) in the research areas will maintain appropriate records in accordance with the provisions of this chapter.

(3) VA Form 10-2638 will indicate the experiment number, date, and any other identifying information available to provide satisfactory proof-of-use record for each dose of drug administered.

d. Inspection

(1) VA Form 10-2638 and the corresponding drug will be made available for monthly inspection by the appointed Controlled Substances Inspecting Official.

(2) VA Form 10-2638, when completed, will be returned to the pharmacy.

e. Storage

(1) Schedule II substances must be securely stored under double lock.

(2) Access will be limited to employees specifically authorized in writing to have access to the controlled substances.

5.10 INSPECTION OF Schedule II SUBSTANCES

a. General

(1) These substances will consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.12.

(2) These substances will be inventoried according to DEA regulations. The controlled substances inventory record must be a separate listing. Inspection of wards and clinics will be conducted in accordance with VHS&RA Manual M-2, part I, chapter 2.

b. Responsibility

Directors of VA medical centers, domiciliary, outpatient clinics, and regional offices with outpatient clinics are responsible for establishing an adequate and comprehensive system of inspection for Schedule II substances to ensure safety and control of stocks. The Director at each facility is responsible to reacquaint the staff with all current VA directives, to include those relating to physical security. Written records of such inspections will be maintained by the Director. The Director must ensure that a program for orientation and training of inspecting officials is established and followed.

c. Inspecting Officials

One or more responsible inspecting official(s) (who will not be pharmacists, nurses, physicians, or supply officials) will be appointed, in writing, by the Director. At the smaller facilities, three or four inspectors should be trained and appointed. Larger facilities will require substantially more trained inspectors. No single inspecting official will conduct more than six

monthly inspections in any 12-month period and will not inspect the same area consecutively.

d. Frequency

A monthly unannounced narcotic inspection will include accurate accountability of all Schedule II substances which the inspector must certify to by physical count. No inspector will inspect any one area 2 months consecutively.

e. Areas

Areas to be inspected are A&MM, pharmacy, wards, clinics, laboratories, and all other areas of end use having Schedule II substances drug stock. In cases of inaccuracy in balance of records, the inspecting official(s) will report the discrepancy to the Chief of Pharmacy Service, who will determine the cause. A report of findings will be made to the Director, who will take indicated corrective action.

f. A&MM Issues

Issues of Schedule II substances from A&MM Service will be made directly to the pharmacy in accordance with VA Manual MP-2, subchapter E, section 108.27.5103-7(e). A&MM procedures are unchanged in use of regular voucher number series for card input and filing. In addition to the Property Voucher Register, all issues of Schedule II substances, posted and unposted, will be assigned a consecutive document number by A&MM Service from a separate Controlled Substance Register. The register will show: document control number, date of receipt by pharmacist, department number or location of pharmacy receiving issue, and regularly assigned voucher number. A copy of each voucher listed in this register will be given to the facility inspection official monthly, prior to inspection.

g. Physical Inventory

The physical inventory and inspection of pharmacy stocks and records (VA Forms 10-2320, 10-2638, and 2577d) will be conducted in the presence of the Chief of Pharmacy Service, or the designee. The inspecting official will compare entries on the voucher copies furnished to them by A&MM Service against all entries of quantities received on VA Form 10-2320 in the pharmacy. An actual physical count will be taken and reconciled for accuracy and completeness. The calculations (quantity received plus previous balance minus quantity dispensed equals present balance) will be accomplished and proved for each drug or preparation during each inspection. The inspecting official(s) will date and sign VA Form 10-2320 for each drug or preparation at the time of inspection after taking a physical inventory and reviewing receiving and dispensing records, checking calculations, and certifying the accuracy of the record.

h. CFR (Code of Federal Regulations)

Current copies of 21 CFR Part 1300 shall be on hand in the offices of the Chiefs, Pharmacy Service and the Chiefs, A&MM Service.

5.11 SCHEDULE III, IV, V SUBSTANCES

a. Ordering, Receiving, and Bulk Compounding

(1) Pharmacy stock requirements for Schedules III, IV, and V substances will be ordered from A&MM Service on separate request forms in accordance with current supply procedures.

(2) On delivery from supply, the responsible pharmacy designee will check receipts for items issued for accuracy before signing and dating the original and pharmacy copy of the receiving document. Discrepancies will be reconciled with the Chief, A&MM Service, or a designee, before supplies are accepted by the pharmacist.

(3) Bulk quantities of Schedules III, IV, V substances will be stored in an appropriately secured area.

(4) When empty, containers for Schedules III, IV, V substances for inpatient use will be returned to pharmacy.

b. Dispensing

(1) Schedule III, IV, V substances will be dispensed to wards and clinics, via unit dose, ward, stock or automatic replenishment. VA Form 10-2566-1 (sheet), Doctor's Orders, or another appropriate computer generated form, lists only these substances, and will be signed by the physician, dentist, registered nurse, or licensed practical nurse only.

(2) Usage rate records of Schedule III, IV, V substances dispensed/replenished to wards and clinics will be monitored by the pharmacy.

(3) Schedule III, IV, V substances returned from wards and clinics and determined by the pharmacist to be suitable for reissue will be returned to stock. A record of these returns will be on VA Form 10-2566-1, or other approved form, listing these drugs only.

(4) Schedule III, IV, V substances dispensed/replenished to wards and clinics via unit dose system will be dispensed/replenished in accordance with unit dose dispensing procedures.

(5) Schedule III, IV, V substances for individual patients (ambulatory or special preparations for inpatients) will be dispensed/replenished by the pharmacist only on presentation of a properly completed VA Form 10-2577d, or other prescriptions form. The letter "C," in red ink, not less than 1-inch high, will be stamped on the lower right corner.

c. Records and Forms Requirements

Filing of all Schedule III, IV, V substances will be in accordance with 21 CFR 1304.04(h)(2).

d. Disposal of Excess or Expired III, IV, V Substances

Disposal will be in accordance with DEA regulations, see paragraph 5.08 f. and 21 CFR 1307.21.

e. Alternate methods of ordering Schedule III, IV, V substances may be developed, utilizing computerized systems, as long as they comply with 21 CFR Part 1300.

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CHAPTER 6. INVESTIGATIONAL DRUGS

6.01 GENERAL

a. Definitions

(1) **IND (Investigational drug)** is a medication for which a new drug application has been filed with the FDA (Food and Drug Administration). An investigational drug may be a new chemical compound which has not been released by the FDA for general use. Or, it may be an approved drug which may be used for an unapproved or approved use in a controlled, randomized, or blended clinical trial. Investigational drugs usually are not available through commercial channels.

(2) **PI (principal investigator)** is the individual who is accountable for the proposal, the protocol, performance, and culmination of a research or development project.

(3) **Cooperative study** is a project or program of research at two or more health care facilities using a common protocol so that data obtained at all participating facilities can be treated as though from a single source.

(4) **Humanitarian use** is the use of an investigational drug:

(a) In an emergency or life-threatening situation; or

(b) Where all standard and innovative treatment alternatives have been exhausted and the only remaining alternative is the use of an investigational drug; or

(c) Where a patient already on an investigational drug protocol at one facility is admitted to another facility and must be controlled on the medication.

Humanitarian use is usually a one-time/one patient use.

(5) **Treatment IND Use** is an investigational drug where the FDA has granted approval for a drug to be used by a qualified investigator in patients with a serious or life-threatening illness. There is a nationally approved treatment protocol for which the patient must be eligible and have a specific treatment plan. This should not be confused with the Humanitarian Use program. These investigational drugs may be charged for by the sponsor and therefore local policies regarding these drugs must be established.

b. Basic Policy

(1) Each facility carrying out investigational drug studies must assure through written policies and procedures that adequate safeguards are in place to protect the patient, the staff, the facility, and the quality of the study.

(2) All investigational drug studies must, consistent with applicable laws, regulations, and VA (Department of Veterans Affairs) policy, be carried out by

properly qualified investigators under protocols approved by the local R&D (Research and Development) Committee.

(3) Patients must be given complete information about the study objectives, risks, and benefits, and must give written, informed consent to participation in the study.

6.02 PHARMACY RESPONSIBILITIES

a. Pharmacy Service, as part of its function in the local research committee(s), is responsible for determination that all investigational drugs have been properly approved prior to order, receipt, storage, or use.

b. Pharmacy Service will be responsible for the receipt, custody, storage, and dispensing of all drugs in clinical stages of evaluation, or used under investigational protocols. Investigational drugs may be stored in any appropriate storage area under custody and control of the Chief of Pharmacy Service.

c. Pharmacy Service will be responsible for maintaining a file of investigational drug protocols, correspondence with the FDA, drug source, local investigator, other involved authorities, and assuring that VA Form 10-1086 an Informed Consent Form, i.e. the Agreement to Participated in Research By or Under the Direction of the VA, has been obtained prior to dispensing.

d. Pharmacy Service will be responsible for maintaining a log of all transactions involving receipt, dispensing, and disposition of unused stocks of investigational drugs.

e. Pharmacy Service and the PI will prepare and make available and distribute to using services (nursing stations, clinics) summaries of basic information regarding investigational drugs approved for use, prior to dispensing the investigational drug.

f. The PI will supply to Pharmacy Service information on each patient receiving an investigational drug, with emphasis on documentation of allergies, toxicities, or adverse drug reactions related to the investigational drug, or interactions between the investigational drug and other drug therapy.

g. Pharmacy Service shall be represented on the local R&D Committee as either a member or ex-officio member. The Committee will not approve a proposal involving investigational drugs unless the Chief, Pharmacy Service, determines that pharmacy resources are adequate or that satisfactory provisions have been made for reimbursement (when applicable).

6.03 RECEIPT, CONTROL, CUSTODY, DISPENSING

a. Regardless of source, all investigational drugs will be delivered to the pharmacy for receipt, storage, and distribution. All investigational drugs will remain under control and in the custody of Pharmacy Service until time of dispensing. VA Form 10-9012 Investigational Drug Information Record must be provided to the pharmacy by the PI not later than the time of first receipt of the investigational drug.

b. Any practitioner other than the PI wishing to use an investigational drug may contact Pharmacy Service and will be given information concerning appropriate procedures which should be followed in order to be added to the protocol as an additional investigator.

c. Investigational drugs will not be obtained from other facilities or principal investigators without adherence to protocol procedures, except as noted under humanitarian or treatment IND use.

d. Investigational drug stocks will be kept separate from other drugs and dispensed only on the properly written order of the practitioner authorized to use the drug.

e. The practitioner authorized to use the investigational drug will provide pharmacy with a direct copy of the signed informed consent document with the first written order for the investigational drug for each patient added to the protocol.

f. In addition to customary prescription label data and appropriate auxiliary, caution, or warning labels, all investigational drug labels will include the following legend in capital letters: **"CAUTION - NEW DRUG: LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE."**

g. An investigational drug log will be maintained containing the following information where applicable:

- (1) Name of the drug,
- (2) Manufacturer or other source,
- (3) Date of receipt of the drug,
- (4) Quantity received,
- (5) Expiration date,
- (6) Control number,
- (7) Data protocol approved,
- (8) Name of authorized practitioner signing the prescription,
- (9) Name of patient receiving the medication,
- (10) Serial number of the prescription,
- (11) Quantity dispensed,
- (12) Balance remaining after the transaction,
- (13) Signed initials of the dispensing pharmacist, and

(14) A final entry will be made when the use of the investigational drug is discontinued. This entry will document the date of termination of the use of the drug, the quantity remaining, and the action taken to dispose of the balance on hand.

6.04 HUMANITARIAN USE OF AN INVESTIGATIONAL DRUG

a. Occasionally, it may become necessary to treat a patient with an investigational drug that he received while undergoing treatment at another facility or as a compassionate treatment with the investigational drug as a "last hope." In those cases the following steps should be taken for humanitarian use of the drug:

(1) The responsible staff practitioner should communicate with the Chief of Staff, the pharmacist responsible for the investigational drug use, and the local research committee. Initial communication within the facility may be telephonic to expedite patient care.

(2) After the responsible staff practitioner obtains tentative approval for use of the drug on the patient, the request should be reduced to writing as follows:

(a) A brief case report including patient data and diagnosis.

(b) The reason for requesting approval to use the drug.

(c) Literature or reference material to support the request.

(d) The name of the PI and the local practitioner responsible for care of the patients.

b. The Chief of Staff of the requesting facility will communicate to VA Central Office and the Executive Committee on Therapeutic Agents via teletype all essential data listed above requesting priority approval of the use of the drug. VA Central Office approval will be confirmed by return teletype. A copy of the written approval will be forwarded to Pharmacy Service.

c. The requesting practitioner will provide Pharmacy Service with a copy of the drug protocol, signed Agreement to Participated in Research By or Under the Direction of the VA, VA Form 10-1086, and an Investigational Drug Information Record, VA Form 10-9012, and a properly completed order for the drug prior to administration. All supplies of the drug must be delivered to the pharmacy as with any other investigational drug.

d. The practitioner must prepare a preliminary report to the local P&T (Pharmacy and Therapeutics) Committee within 90 days of initiation of therapy, and a final summary report upon termination of the drug. The local P&T Committee will forward the report(s) to VA Central Office.

e. All documentation of use of drugs obtained for humanitarian or compassionate use will be the same as other drugs as outlined in paragraph 6.03 g.

6.05 USE OF APPROVED DRUGS FOR UNAPPROVED INDICATIONS

a. A physician may use a marketed drug in an unapproved manner without obtaining an IND if it is given for therapeutic rather than investigational purposes.

b. The Chief of Staff and/or Director may apply more stringent controls regarding such drug usage.

6.06 VA COOPERATIVE STUDIES

a. In the case of a VA Cooperative Study employing investigational drugs, the Cooperative Studies Program Clinical Research Pharmacy at the VA Medical Center, Albuquerque, New Mexico, will prepare VA Form 10-9012, for the Pharmacy Service of the participating investigator's VA medical center. The Chief, Pharmacy Service of the participating investigator's VA medical center will also receive a copy of FD Form 1571 the Investigational New Drug Application,,

a copy of the IND letter from the FDA, and FD Form 1573 Statement of the Investigator for the participating investigator from the Cooperative Studies Program Clinical Research Pharmacy. A copy of the "Report of the Subcommittee on Human Studies" indicating approval of the study should be forwarded from the local research office to the appropriate Cooperative Studies Program Coordinating Center assisting the study.

b. The Cooperative Studies Program Clinical Research Pharmacy will be responsible for obtaining the investigational drug and for distributing it to the Chief, Pharmacy Service of each authorized participating medical center. The Pharmacy Service of each participating medical center will maintain records on the investigational drug dispensed, and will return the unused drug when participation in the cooperative study by that medical center is terminated.

6.07 FORMS FOR USE WITH INVESTIGATIONAL DRUGS

a. The following are VA forms for use in documentation of use of investigational drugs:

(1) VA Form 10-1223, Report of Subcommittee on Human Studies.

(2) VA Form 10-1086, Agreement to Participated in Research By or Under the Direction of the VA (Part I and Part II).

(3) VA Form 10-9012, Investigational Drug Information Record.

b. Appendix A is a sample telegraphic message used for requesting approval for humanitarian use of drugs.

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b. Affiliated Education Programs

(1) In accordance with VHS&RA (Veterans Health Services and Research Administration) Manual M-8, part II, chapter 2, academic affiliations strongly support a broad policy of cooperation and professional interchange with educational institutions. Affiliated education programs for the associated health professions assist in: attracting students and retaining them after graduation to provide quality health care to veterans; enhancing the professional development of VA personnel as a result of the student-teacher relationship; and utilizing VHS&RA professional resources and clinical facilities to provide an adequate supply of health care personnel for VA and the nation.

(2) To establish affiliated education programs for pharmacy, policies are provided in M-8, part II, chapter 2, paragraphs 2.08, 2.09, 2.10, and 2.34. The types of pharmacy students eligible for academic affiliations are Pharmacy Residents, Doctors of Pharmacy, Masters and Baccalaureate Pharmacists, and Pharmacy Technicians.

(3) Approved VA accredited Pharmacy Residency Programs, i.e., Hospital, Clinical, and Clinical Specialty, are provided funding support by OAA (Office of Academic Affairs) (143C). All other pharmacy student trainees are appointed on a without compensation basis. (M-8, part II, chapter 2, paragraph 2.34.)

7.04 RESPONSIBILITY AND CONTROL

The Chief, Pharmacy Service, will be responsible for planning and implementing educational and training programs. Each Pharmacy Service will establish policies and procedures for training and continuing education programs.

7.05 PLANNING AND IMPLEMENTATION

Provisions will be made for VA pharmacy personnel to participate in the identification of their continuing educational needs and in the plans for meeting competency requirements. An interdisciplinary approach to sponsoring, planning, and implementing educational activities is encouraged. The continuing education programs will be consistent with the overall goals and objectives of VHS&RA OAA (143). Whenever feasible and appropriate, efforts should be made to utilize facility directed RMEC (Regional Medical Education Center) administered VA medical center initiated resources or professional organizations to support education programs. Adequate staffing, space, and time allotment for any educational activity should be sufficient to assure achievement of the objectives. Provisions should be made for pharmacy employees to have time available to devote to these educational activities. Facilities approved for use of Tuition Support Program funds for pharmacists may use these funds to support continuing education needs.

7.06 DEFINITIONS

The following are classifications of trainees who may typically be found in Pharmacy Service:

a. **VA Pharmacy Residency**

(1) **Pharmacy Resident.** Enrolled in or graduate of a pharmacy program accredited by ACPE (American Council on Pharmaceutical Education), and appointed to a VA pharmacy residency program accredited by ASHP (American Society of Hospital Pharmacists).

(2) **Hospital Resident.** Enrolled in or graduate of a masters or pharmacy doctorate program accredited by ACPE, and a member or applicant for membership of ASHP. This residency may be for 1 year (40 hours per week) or 2 years (28 hours per week).

(3) **Clinical Resident.** Post-masters or postdoctoral graduate of a school of pharmacy accredited by ACPE, and a member or applicant for membership of ASHP. The resident must have had prior experience in hospital pharmacy practice before entering this residency. The residency is for 1 year, full-time.

(4) **Clinical Specialty Resident.** Postdoctoral graduate of a school of pharmacy accredited by ACPE, and a member or applicant for membership of ASHP. The resident must have had prior experience in pharmacy practice before entering this residency. The residency is for 1 year, full-time.

b. Administrative Training

Pharmacy Management Trainee. A licensed pharmacist and VA employee who is developing competent management skills and knowledge through graduate academic course work at a VA facility designated by VA Central Office for such training. This trainee is under the supervision of the Chief, Pharmacy Service. This is administrative training (continuing education) funded by OAA (143).

c. Affiliated Training

(1) **Clinical Clerk.** Baccalaureate, Masters, or Doctor of Pharmacy student receiving clinically-oriented pharmacy training at the facility. These individuals are generally under university-affiliated supervision, and receive academic credit for licensure.

(2) **Extern.** Baccalaureate, Masters, or Doctor of Pharmacy students receiving affiliated training at the facility. This is for academic credit, and is generally credited for licensure.

d. Local Training

(1) **Intern.** An undergraduate pharmacy student or a graduate pharmacist obtaining practical experience for purposes of licensure.

(2) **Fellow.** A licensed pharmacist, or a graduate eligible for licensure, receiving postgraduate training at the facility, with the primary objective of doing clinical research. It may or may not be part of an advanced academic degree program.

(3) **Technician Trainee.** An undergraduate student receiving practical and didactic training at the facility in order to meet certain minimum standards as required by VA or provided as a guide by State regulations. Generally, the trainee must always be under the supervision of a qualified technician or pharmacist preceptor.

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CHAPTER 8. PROFESSIONAL AND SCIENTIFIC LITERATURE

8.01 GENERAL

Information is central to the practice of modern pharmacy. Pharmacy has become a consultative profession where pharmacists apply clinical drug information that directly impacts patient care. Pharmacy is evolving into a clinical knowledge-based profession where the pharmacist interprets and uses drug data aimed at the optimal utilization of drugs in patients. Pharmacy Service will gather and maintain current information on drug products, pharmaceutical techniques, clinical drug therapeutics, and other developments in the use of drugs.

8.02 MINIMUM REQUIREMENTS

a. Professional References. Current editions of the references listed below shall be maintained in the pharmacy as professional information sources. Additional copies of the references listed below may be kept at the medical center library on the recommendation of the Chief, Pharmacy Service.

(1)

U.S. Pharmacopeia/National Formulary

United States Pharmacopeial Convention, Inc.

12601 Twinbrook Parkway

Rockville, MD 20852

(2)

Remington's Pharmaceutical Sciences

Mack Publishing Company

20th and Northampton Streets

Easton, PA 18042

(3)

Approved Drug Products with Therapeutic Equivalency Evaluations

(and Supplements)

United States Department of Health and Human Services

Government Printing Office

Washington, DC 20402

(4)

Facts and Comparisons (and Supplements)

Kastrup EK and Olin BR
Facts and Comparisons Division
JB Lippincott Company
111 West Port Plaza, Suite 423
St. Louis, MO 63146

(5)
Current Medical Diagnosis and Treatment

Krupp MA, Chatton MJ, and Tierney LM
Lange Medical Publications
Los Altos, CA 94022

(6)
Merck Index

Merck and Company, Inc.
Publications Department
Rahway, NJ 07065

(7)
Medical Dictionary

Dorland's Illustrated
W.R. Sanders Company
218 West Washington Square
Philadelphia, PA 19105

(8)
The Pharmacological Basis of Therapeutics

Gilman AG, Goodman LS, Rall TW, Murad F
Macmillan Publishing Company
866 Third Avenue
New York, NY 10022

(9)
Drug Interactions

Hansten PD
Lea and Febiger
600 Washington Square
Philadelphia, PA 19106

(10)
Clinical Toxicology of Commercial Products

Gosselin RE, Smith RP, Hodge HC
Williams and Wilkins
428 East Preston Street
Baltimore, MD 21202

(11)
Code of Federal Regulations 21

The Office of the Federal Register
National Archives and Records Service
General Services Administration

6-74

Washington, DC 20408

(12)
Federal Law Handbook

Nielsen Jr

Lea and Febiger

600 Washington Square

Philadelphia, PA 19106

(13)
American Hospital Formulary Service, Drug Information

(and Supplements)

American Society of Hospital Pharmacists

4630 Montgomery Avenue

Bethesda, MD 20814

(14)
Handbook on Injectable Drugs

Trissel LA

American Society of Hospital Pharmacists

4630 Montgomery Avenue

Bethesda, MD 20814

(15)
Physician's Desk Reference (updated annually)

Medical Economics Company, Inc.

Oradell, NJ 07649

(16)
Handbook of Nonprescription Drugs

American Pharmaceutical Association

2215 Constitution Avenue NW

Washington, DC 20037

6-75

Knoben JE, Anderson PO
Drug Intelligence Publications
P. O. Box 1903
Spokane, WA 99210

(18)
Applied Therapeutics

Katcher BS, Young LY, Koda-Kimble MA
Applied Therapeutics, Inc.
P.O. Box 1903
Spokane, WA 99210

(19)
Martindale. The Extra Pharmacopeia

Reynolds JEF
The Pharmaceutical Press
London, England

(20)
Guide To Parenteral Admixtures Drugs

King JC
Cutter Labs
8900 Manchester Rd.
St. Louis, MO

b. **Current Editions of Recognized Texts.** Recognized textbooks dealing with pharmacy, pharmacology, toxicology, and clinical therapeutics shall be available at the medical center. These textbooks may be maintained at the medical center library for greater accessibility to all health care providers. Alternatively, they may be maintained as part of the core library of a drug information or poison control center if one operates within the institution. Pharmacy Service will be responsible for notifying the Chief, Library Service, through memorandum, about new textbook editions as they become available for procurement.

(1)
Handbook of Poisons

Dreisback RH, Robertson WU
Lange Medical Publications
Los Altos, CA 94022

(2)
The Use of Antibiotics

Kucers A, Bennett N
W. Heinemann Medical Books Ltd.
23 Bedford Square
London WC1B 3HH, England

or

(3)
Manual of Antibiotics and Infectious Disease

Conte JE, Barriere SL
Lea and Febiger
600 Washington Square
Philadelphia, PA 19106

or

(4)
Evaluation of Drug Interactions

American Pharmaceutical Association
2215 Constitution Avenue NW
Washington, DC 20037

(5)
American Drug Index

Billups NF

JB Lippincott Company

Philadelphia, PA 19105

(6)
Cecil-Loeb Textbook of Medicine

Beeson and McDermott

or

(7)
Drug Interaction Facts

Mangini RJ

Facts and Comparisons Division

JB Lippincott Company

111 West Port Plaza, Suite 423

St. Louis, MO 63146

W.B. Sanders Company

West Washington Square

Philadelphia, PA 19105

or

(8)
Harrison's Principles of Internal Medicine

Petersdorf RG, et al

McGraw Hill Book Company

New York, NY 10036

(9)
Pharmacy Law Digest

Fink JL, Marquardt KW, Simonsmeier LM

Facts and Comparisons Division

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JB Lippincott Company
111 West Port Plaza, Suite 423
St. Louis, MO 63146

(10)
Basic and Clinical Pharmacology

Katzung BG
Lange Medical Publications
Los Altos, CA 94022

(11)
Side Effects of Drugs

Dukes MNG
Excerpta Medica
American Elsevier Publishing Company
52 Vanderbilt Avenue
New York, NY 10017

(12)
Manual of Medical Therapeutics

Orland MJ, Saltman RJ
Little Brown and Company
Boston, MA 02106

(13)
Clinical Pharmacy and Therapeutics

Herfindal ET, Hirschman JL
Williams and Wilkins
428 East Preston Street
Baltimore, MD 21202

See-Lasley K, Ignoffo RJ
The CV Mosby Company
11830 Westline Industrial Drive
St. Louis, MO 63146

Evans WE, Schentag JJ, Jusko WJ
Applied Therapeutics, Inc.
P.O. Box 1903
Spokane, WA 99210

Lamy PP
John Wright, PSG Inc.
545 Great Road
Littleton, MA 01460

c. **Professional Journals.** At the discretion of the Chief, Pharmacy Service, 7 of the 12 journals listed below should be maintained in the pharmacy as daily working references:

American Society of Hospital Pharmacists
4630 Montgomery Avenue
Bethesda, MD 20814

American Pharmaceutical Association
2215 Constitution Avenue, NW

Washington, DC 20037

(3)
Journal of Clinical Pharmacology

JB Lippincott
East Washington Square
Philadelphia, PA 19105

(4)
The Medical Letter on Drugs and Therapeutics

The Medical Letter, Inc.
56 Harrison Street
New Rochelle, NY 10801

(5)
Clin Alert

Clin Alert Inc
143 Old Marlton Pike
Medford, NJ 08055

(6)
Pharmindex

Skyline Publishers, Inc.
P.O. Box 1029
Portland, OR 97207

(7)
Drug Intelligence and Clinical Pharmacy

Harvey Whitney Books
P.O. Box 42696
Cincinnati, OH 45242

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(8)
Clinical Pharmacy

American Society of Hospital Pharmacists
4630 Montgomery Avenue
Bethesda, MD 20814

(9)
Hospital Formulary

Modern Medicine Publications
7500 Old Oak Boulevard
Cleveland, OH 44130

(10)
Pharmacy Times

Romaine Pierson Publishers
80 Shore Road
Port Washington, NY 11050

(11)
Pharmacotherapy

Pharmacotherapy Publications, Inc.
11 Nassau Street
Boston, PA 02111

(12)
U.S. Pharmacist

Jobson Publishing Corp.
352 Park Avenue South
New York, NY 10010

The Chief, Pharmacy Service, will determine when journals are no longer needed in the pharmacy. The Chief, Pharmacy Service, and the Chief, Library Service, will determine which journals should be bound.

d. **Professional Drug Literature Files.** Pharmacy Service will collect and maintain printed information on drug products. The information collected shall be maintained in an organized filing system to ensure accessibility and may be

restricted to information on those drugs that are approved by the medical center's P&T (Pharmacy and Therapeutics) Committee. In lieu of drug literature files, a broad based drug information system may be provided; e.g.,

(1)

International Pharmaceutical Abstracts

American Society of Hospital Pharmacists

4630 Montgomery Avenue

Bethesda, MD 20814

or

(2)

Iowa Drug Information System

Westlawn, Box 330

The University of Iowa

Iowa City, IA 52242

or

(3)

Drugdex Information System

Micromedex, Inc.

660 Bannock St. - Suite 300

Denver, CO 80204

(1 800 525-9083)

e. **Formulary System.** Pharmacy Service shall establish and maintain a formulary listing of all drugs approved for use by the medical center's P&T Committee. In addition, the formulary may include information on Pharmacy Service policies and services, annotations of special classifications for drugs (e.g., prescription, over-the-counter, restricted to specific service, etc.), and relative or actual costs. The medical center drug formulary shall be readily available at all nursing units and clinics for use by prescribers. Formularies will be available in the office of the Chief of Staff, office of the Chief, Pharmacy Service, and any other locations where such information may help prescribers. Copies of the American Hospital Formulary Service, Drug Information, will also be distributed to nursing stations and clinics to enhance the information provided by the formulary.

f. **Drug Monographs.** Pharmacy Service shall be responsible for the preparation of drug monographs for pharmaceuticals that are requested for formulary listing. The monographs should contain a critical review of published data regarding the safety and efficacy of the drug. Comparisons to similar agents should be presented when available. Drug monographs will be used by members of the P&T Committee to aid in the decision to add the drug to the medical center formulary.

g. **Drug Information Access.** Pharmacy Service shall explore means to access electronic databases for rapid retrieval of drug information. Such databases may consist of on-line systems accessed through modem, e.g., Medline, or independent systems. In addition, particularly if electronic access is difficult, Pharmacy Service shall have the services of a Drug Information Center readily available for consultation. The telephone number for such a center shall be prominently located and pharmacists will be advised to use the service to obtain information as necessary.

8.03 ACTIVE DRUG INFORMATION DISSEMINATION

a. **Newsletter.** Pharmacy Service shall endeavor to actively disseminate information to physicians, pharmacists, nurses, and other health care providers. This may be accomplished through the use of an institutional newsletter distributed to health care providers. Information may consist of pharmacy prescribing regulations, warnings on new or unusual drug side effects, new drug reviews, current literature reviews, cost comparisons, and other information that will enhance prescribing practices.

b. **Other Methods.** Accepted methods for active drug information dissemination include in-services, conferences, and formal lectures.

8.04 DRUG INFORMATION SERVICES

a. Pharmacy Service is responsible for the provision of drug information to health care professionals at the medical center. Drug information can be provided with the use of the resources described in the preceding sections. Pharmacy Service shall document the provision of drug information as part of the quality assurance activities.

b. Pharmacy Service shall provide drug information to patients at their request. Information so provided is intended to increase patient understanding of the importance of their drug therapy and to increase patient drug compliance.

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CHAPTER 9. DRUG CONTROLS AND ACCOUNTABILITY

9.01 GENERAL

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 drug distribution, therapeutic monitoring, provision of drug information, drug usage evaluation, intervention to change prescribing habits, consultative services, and other measures designed to ensure the safe and efficacious use of drug therapy. Drug Control and accountability must include non-distribution as well as distributive aspects of drug use control.

9.02 OBJECTIVES

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

9.03 FORMS CONTROL

Pharmacy Service will be responsible for the storage and issuance of all VA Form 10-2577d, Prescription Forms, and VA Form 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 will be 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.

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.

9.06 QUALITY MANAGEMENT, UTILIZATION REVIEW, RISK MANAGEMENT, AND QUALITY

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

b. Pharmacy Service will establish a Quality Assurance Committee at the VA medical center. The role of the committee is to assure that the Pharmacy Service Quality Assurance Program is consistent with the current standards outlined by the JCAHO (Joint Commission on Accreditation of Healthcare Organizations).

(1) Pharmacy Service will have 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. Nondistributive (clinical) as well as distributive functions will be 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, it 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 Assurance Committee, the Utilization Review Committee, the Infection Control Committee, and the Drug Use Evaluation Committee.

d. Adverse Drug Reactions will be monitored and trended by the Pharmacy Service representative to the medical center P&T (Pharmacy and Therapeutics) Committee. Reporting of adverse drug reactions will be conducted as outlined in M-2, part I, chapter 3, paragraph 3.06b.

e. Medication errors originating in Pharmacy Service will be monitored and trended. Medication errors will be categorized by type (e.g., unit dose, IV, window, or mailout). Action is taken to identify and correct contributing factors to medication errors. Such action is documented and evaluated for effectiveness. Medication errors will be reported as required by VHS&RA (Veterans Health Services and Research Administration) Supplement, MP-1, part I, chapter 2, change 43.

f. Pharmacy Service will participate in and facilitate 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 (ASHP (American Society of Hospital Pharmacists) 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 will participate in Boards of Investigation where incidents may have been precipitated by drug therapy or medication errors.

h. All quality assurance information is considered confidential as outlined by 38 U.S.C. 3305. The use of provider specific quality assurance information in disciplinary actions is strictly prohibited. When quality assurance studies indicate that there may be a provider-associated problem, data must be recollected through an administrative review process. In this process, information is collected in a fair and representative sampling process should be utilized.

i. Pharmacy Service will maintain a quality control program which includes, but is not limited to:

(1) Pharmacy Service IV additive programs will have quality control programs in place as outlined by 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, will be generated by Pharmacy Service and referred to the Office of Acquisition and Materiel Managements.