

December 13, 1993

1. Transmitted is a revision of the Department of Veterans Affairs, Veterans Health Administration, Manual M-2, "Clinical Programs," Part I, "General," Chapter 3, "Pharmacy and Therapeutics (P&T) Committee."

2. Principal changes are:

a. Paragraph 3.02: Revision of P&T provisions to reference Joint Commission for Accreditation of Healthcare Organizations and/or American Society of Hospital Pharmacists guidelines on the operation of P&T committees.

b. Paragraph 3.05: Decentralization of investigational drug approvals;

c. Paragraph 3.06: Revision of adverse drug event reporting to match FDA's MedWatch system.

3. Filing Instructions

Remove pages

Insert pages

iii through vi

iii through vi

3-i

3-i through 3-ii

3-1 through 3-6

3-1 through 3-8

4. RESCISSIONS: M-2, Part I, Chapter 3, change 71, dated January 20, 1984 and contents page 3-i, dated February 9, 1990; Rescission pages iii and iv, dated August 9, 1993, and rescission pages v and vi, dated August 7, 1992; and VHA Directive 10-92-070

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

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RESCISSIONS

The following material is rescinded.

1. COMPLETE RESCISSIONS

a. Manuals

M-2, Part I, changes 2 through 5 through 9, 11, 12, 13, 14, 16, 18 through 21, 25, 30, 32 through 40, 41, 44, 45, 49, 50, 51, 52, 55, 57, 60.

M-2, Part I, Chapter 3, and change 71 dated January 20, 1984.

VHA Supplement MP-1, Part I, Chapter 2, Section A and Appendices D and E, change 43, dated October 27, 1987

VHA Supplement MP-1, Part I, Chapter 2, Section A, change 44, dated July 26, 1991

b. Interim Issues

II 10-156

II 10-161

II 10-184

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II 10-381

II 10-68-31

II 10-71-33

II 10-71-26 by M-2, part I, chg. 67

II 10-82-53 de facto by chg. 74

II 10-83-7 by chg. 74

c. Circulars/Directives

261, 1946, Sec.1

10-62-70

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10-91-059

10-92-056

d. Regulations and Procedure

R&P 6202

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R&P 6206

e. Technical Bulletins

Par. 2, TB 10A-191
 Pars. 1b, 2 through 5, 6a and 9c, TB 10A-246
 TB 10A-256
 TB 10A-295 (except sec. XXI)
 TB 10A-359
 TB 10A-324 (This completes the rescission of TB 10A-324.)

f. AB Station Letters and Other Communications

Date

Subject

December	5,	1949
Officer of the Day Reports		
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g. Instructions (pertaining to Public Law 702, 80th Cong., as amended)

Pars. 2d and 2e, Inst. 1-B

Inst. 1C

Inst. 1-D

2. LIMITED RESCISSIONS

The following material is rescinded insofar as it pertains to this manual:

a. Manuals

M10-3, par. 112f and 115h

M10-6, pars. 9b, 42e, 70c, 86, 132h, 129f, and 169

M10-11, pars. 22b, 92e, 96d, 133b, and 172

b. Interim Issues

II 10-292, pars. I, II, III, Appendix A

c. Circulars

10-65-57, pars. 2 and 3

d. Regulations and Procedure

R&P 6130

e. Technical Bulletins

TB 10A-324

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RESCISSIONS

1. Manual

M-2, Part I, Chapter 3, and change 71 dated January 20, 1984.

2. Directives

10-92-070

CHAPTER 3. PHARMACY AND THERAPEUTICS (P&T) COMMITTEE

3.01 POLICY

Each independent Department of Veterans Affairs (VA) health care facility must have an established Pharmacy and Therapeutics (P&T) Committee. The P&T Committee's functions are performed by the medical staff, in cooperation with Pharmacy Service, Nursing Service, Management, and, as required, other services.

3.02 FUNCTIONS

a. The P&T Committee's monitoring function includes at least those functions outlined in the most current Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Accreditation Manual for Hospitals and the American Society of Hospital Pharmacists (ASHP) Statement on the P&T Committee.

b. The P&T Committee will:

(1) Consider recommendations or requests from the staff for medications available in interstate commerce which are non-formulary at the medical center.

(2) Ensure that pharmaceuticals and expendable medical supplies are purchased from mandatory contract sources to the maximum extent practicable, and an appropriate waiver is granted for any deviation.

(3) Review requests for authorization of use, or purchase, of a specific brand of pharmaceutical if a pharmaceutical is listed in one of the VA Medication Classification categories by generic name. Exceptions to the generic drug requirement will be determined by the Under Secretary for Health in consultation with the Commissioner of the Food and Drug Administration (FDA). (See M-2, Pt. I, par. 32.03).

3.03 DEVELOPMENT AND MAINTENANCE OF A FORMULARY

The P&T Committee will be responsible for the development and revision of the facility's formulary. The formulary will be developed following the guidelines outlined in the ASHP Technical Assistance Bulletin on Formularies.

a. As requested by members of the Professional Staff, the P&T Committee will review and evaluate data on drugs to approve or disapprove the use of such drugs in the:

- (1) Medical center,
- (2) Outpatient clinic,
- (3) Nursing Home Care Unit (NHCU),
- (4) Domiciliary, and
- (5) Fee-basis Program.

b. Requests for pharmaceuticals to be considered by the P&T Committee will be made using VA Form 10-7144, Drug Request.

3.04 MINUTES

a. A Pharmacy Service representative will serve as the P&T Committee secretary and will be responsible for the P&T Committee minutes.

b. Minutes will be forwarded to the Clinical Executive Board (CEB) for review following approval by the P&T Committee.

c. At a minimum, the minutes will include a record of the discussion and conclusions relating to the following:

- (1) Formulary additions and/or deletions,
- (2) One-time clinical trial approvals,
- (3) Investigation protocols,
- (4) One-time use approvals,
- (5) Drug use evaluation studies,
- (6) Adverse drug events (ADEs), and
- (7) Material Quality Improvement Reports.

3.05 INVESTIGATIONAL DRUGS

a. The P&T Committee at each facility will:

- (1) Evaluate the protocols concerned with the use of investigational drugs.
- (2) Establish an emergency review mechanism for investigational drugs when existing review procedures must be expedited for humanitarian reasons. NOTE: Approval for such uses will be granted locally by the Chairperson, P&T Committee.

b. Investigational Drug Protocol

(1) These procedures include the review of requests for use of investigational drugs for diagnostic or therapeutic use in specific cases.

(a) Medical personnel making such requests must have an Investigational New Drug (IND) number prior to use of the investigational drug. (See M-3, Pt. II, Ch. 5.)

(b) Requests for approval will be limited to drugs which have been, or are being, used by well-qualified clinical investigators, and on which reports, or other communications from investigators are available.

(c) Requests submitted for emergency approval will include:

1. Patient's name;
2. Patient's Social Security Number;
3. Name of drug;

4. Diagnosis;
5. Reasons drug is required;
6. Name, IND number, and VA title of VA physician or dentist responsible for therapy;
7. Literature reference source; and
8. Authorized source of drug.

(2) Upon receipt and approval of an emergency request for approval to use an investigational drug, the Chairman, P&T Committee, at the VA facility will instruct the physician, or dentist, under whose supervision the drug is to be used, to fully inform the patient concerning the:

- (a) Administration of the investigational drug;
- (b) Reasons for its use;
- (c) Inconveniences and hazards which can reasonably be expected; and
- (d) Existence of alternative forms of therapy, rather than the use of the investigational drug.

(3) Consent

(a) The physician must obtain the consent of the patient by signature on VA Form 10-1221, Consent for Use of Investigational Drug for Either Diagnostic or Treatment Purposes by or Under the Direction of the Veterans Administration.

1. If the patient is unconscious, or has been adjudged incompetent by a court, or, as a result of psychiatric disorder is unable to give consent, or is incapable of comprehending the significance of such action or of exercising appropriate judgment, the consent of the patient's legally-authorized representative will be obtained by signature on VA Form 10-1221 in accordance 38 Code of Federal Regulations (CFR) 1734; 17.34a (see M-2, Pt. I, Ch. 23).

2. The VA Form 10-1221, when signed, will be filed in the patient's medical record.

(b) The physician may proceed to administer an investigational drug for therapeutic purposes without obtaining consent when the following conditions exist:

1. If the patient is unable to give consent;
2. A life-threatening situation exists, and it is believed that the patient's only chance for survival is the administration of this drug; and/or
3. The treating physician determines that the obtaining of consent from the patient's representative could result in a delay which would materially increase the hazards to the life or health of the patient.

a. A dated and signed progress note documenting this decision to proceed must be written by the physician.

b. If time permits, reasonable attempts should be made to contact the patient's representative to obtain consent. If time does not permit, or if the representative is not available, such individual should be contacted as promptly as possible to explain what action has been taken, the indications for the action, and the outcome.

c. The signature of the Chief of Staff is required on VA Form 10-1221 in cases where the administration of an investigational drug is based upon an implied consent.

c. Full documentation in the medical record of proper informed consent will be performed in accordance with the requirements of M-2, Part I, Chapter 23.

(4) A preliminary report will be made to the local P&T Committee on results of use of the drug within 90 days of beginning of tests or therapy. A final summary report will be made upon completion of diagnosis or treatment as applicable. (See M-2, Pt. VII, Ch. 6.)

3.06 ADVERSE DRUG EVENTS (ADES)

a. The purpose of the facility's ADE system is to:

(1) Monitor local trends in ADEs and identify opportunities to prevent future ADEs; and

(2) Provide relevant and timely information to support FDA's MEDWATCH system.

b. Definitions

(1) For VA purposes, an ADE:

(a) Is defined for VA purposes as "an untoward noxious reaction associated with drug use at any dose.

(b) May result from administration of over-the-counter, prescription, or investigational/research drugs.

(c) Includes events occurring from drug withdrawal and significant failure of expected pharmacological action.

NOTE: A proven cause-and-effect relationship between the event and suspected drug(s) is not required before an event is reportable; a reasonable suspicion is sufficient.

(2) For the purposes of FDA's MEDWATCH system, and for drugs currently available in interstate commerce, a serious ADE is defined, for reporting purposes when the patient outcome is:

(a) Death. Report if the patient's death was an outcome of the adverse event. Do not report if the patient happened to die while using a medical product, but there was no suspected association between the event and the use of the product.

(b) Life-threatening. Report if the patient was at substantial risk of dying at the time of the adverse event, due to the ADE, or if the use or continued use of the product might have resulted in the death of the patient.

(c) Hospitalization (initial or prolonged). Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event. Do not report if a patient in the hospital received a medical product and subsequently developed an otherwise non-serious adverse event, unless the adverse event prolonged the hospital stay.

(d) Disability. Report if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

(e) Required Intervention to Prevent Permanent Impairment or Damage. Report if the adverse event required medical or surgical intervention to preclude permanent impairment of a body function or to prevent permanent damage to a body structure due to the use of a medical product. Changes in dosage, discontinuation of therapy and routine treatment with a prescription medication are not in themselves considered serious.

(f) Congenital Anomaly. Report if exposure prior to conception or during pregnancy resulted in an adverse outcome in the child.

(3) FDA's MEDWATCH system seeks reports on ADEs related to the use of new drugs (drugs which have been on the market for less than 3 years), as well as information on unexpected ADEs which are:

(a) Not listed in the current labeling or standard drug references, or

(b) Significantly different from a listed ADE because of their severity or clinical course.

(4) ADEs meeting definitions in subparagraphs (2)(a) through (2)(f) will be defined as constituting "significant" untoward reactions for JCAHO purposes.

NOTE: Reactions caused by blood and blood plasma need not be reported unless a chemical agent other than the basic substance is suspected of being responsible.

c. Reporting Procedures

(1) The P&T Committee will develop and monitor an ADE reporting system.

(a) All facilities will have policies and procedures which describe the operation of the local ADE system. The system must meet, or exceed, requirements mandated by JCAHO and must support FDA's MEDWATCH system.

(b) Local policies and procedures for ADE reporting and monitoring should address at least the following:

1. Routine Identification of Suspected ADEs. Each facility will develop appropriate mechanisms to encourage the identification of suspected ADEs and to facilitate reporting.

a. These approaches may include:

(1) Staff education about ADEs and the importance of identification and reporting;

(2) Use of a central telephone number with an answering machine for staff to report suspected ADEs;

(3) A concurrent surveillance system that monitors the use of drugs that are commonly used in the management of ADEs (e.g., stat doses of epinephrine, corticosteroids, and/or antihistamines);

(4) Use of discharge reviews and other quality assurance activities to identify ADEs.

b. The use of automated surveillance systems provided by Decentralized Hospital Computer Program (DHCP) is encouraged.

2. Notification of the prescriber and appropriate staff members about a suspected ADE.

3. Documentation in the medical record of the ADE, the patient outcome, and any required treatment.

4. Evaluation of the patient by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician to determine if a reportable ADE has occurred.

5. The role of the P&T Committee in evaluating and monitoring ADEs.

6. Requirements for reporting of serious ADEs to the MEDWATCH Program.

7. Requirements for transmitting data electronically to a designated site for regional and national trending when such technology becomes available.

(2) Reports to FDA. Facilities will complete FDA Form 3500, MedWatch, for all serious ADEs relating to drugs and biologicals. Reports of adverse events related to vaccine use should be reported to FDA on VAERS - 1, Vaccine Adverse Event Form.

(a) A copy will be retained for the facility's file for use by the P&T Committee.

(b) The original is forwarded directly to the FDA.

(c) Reports must identify the reporter's address as a VA facility and include the city, state, and commercial phone number of the facility. At a minimum, reports should contain the generic name, brand name, manufacturer, and drug effect/outcome.

(3) Reports to the P&T Committee. All ADE reports will be forwarded to the P&T Committee for monthly review. The committee will assess all relevant data to determine and assess trends and to determine if actions can be taken to prevent future occurrences.

(4) Reports to VA Central Office

(a) When automated transmission becomes available on DHCP, facilities will enter and transmit data on ADEs on a periodic basis to a central location for analysis. NOTE: Stations will be notified when the capability exists.

(b) Facilities identifying alarming problems suspected to be related to drugs (e.g., clusters of cases of serious ADEs) will communicate these as soon as possible by telephone to the Pharmacy Service, VA Central Office at 202-535-7302.

(5) On a quarterly basis, the Executive Committee on Therapeutic Agents (ECTA) will evaluate pharmacoepidemiological information provided by the FDA relating to VA ADE reports for that period. The ECTA will institute policy where warranted to prevent ADEs or to improve reporting.

3.07 USE OF OFFICIAL OR NONPROPRIETARY DRUG NOMENCLATURE

The Veterans' Benefits and Services Act of 1988, Public Law 100-322, requires VA to standardize medical and pharmaceutical items. Physicians and dentists are encouraged to prescribe drugs by generic name (official chemical or nonproprietary).

3.08 APPLICATION OF THE FORMULARY SYSTEM

a. When the proprietary (trade) name of a drug is used on prescription or medication order, the generic equivalent drug will be dispensed regardless of the trade name specified.

(1) The Under Secretary for Health, in consultation with the Commissioner of FDA, may determine that a specific brand of a generic product is dispensed when the stability of the product or issues of patient safety so indicate.

(2) The ECTA is responsible for the review of these exceptions.

(3) The local P&T Committee, with the approval of the CEB, may establish a local policy which will identify additional drugs for single source procurement.

(4) The P&T Committee will establish procedures whereby physicians and dentists may request specific exceptions when it is believed that a particular brand is needed for therapeutic reasons, such as treatment failure or adverse drug event.

b. In the application of the formulary system, prescribers will be furnished VA Form 10-2577F, Prescription Form, and VA Form 10-1158, Doctor's Orders, the DHCP generated Action Profile, or DHCP generated Discharge/Authorized Absence Profile, which provide the means of authorizing the dispensing or administration of drugs at the time the prescription or medication order is written.

(1) Prescribers will be apprised of policies on the operation of the medical center formulary system.

(2) Pharmacists and nurses are authorized to dispense and administer:

(a) Generically equivalent drugs; and

(b) Other "therapeutically" equivalent products as authorized by the P&T Committee.

c. When the prescriber believes a specific brand of pharmaceutical is required for a therapeutic reason (including treatment failure), the prescriber may request the P&T

Committee to approve the procurement on a case by case basis.

NOTE: This provision will not be used routinely to circumvent the general policy on the prescribing, dispensing and administering of drugs by generic name.

3.09 THE DRUG USE EVALUATION AND MEDICATION INDICATORS

The P&T Committee will be responsible, either through the Committee or a subcommittee of the Committee, for having in place a process to meet the drug usage evaluation and medication indicator requirements of JCAHO.