

June 8, 1993

1. Transmitted is a new chapter to the Department of Veterans Affairs, Veterans Health Administration, Manual M-2, "Clinical Affairs," Part VII, "Pharmacy Service," Chapter 10, "Inspection of Controlled Substances."

2. Principal changes include:

a. Chapter 10, is being issued to provide new requirements for lower scheduled controlled substances.

b. Portions of VHA Circular 10-91-107, Increased Accountability for Drugs, are incorporated in this chapter.

3. Filing Instructions

Remove pages

Insert pages

iii through iv

iii through iv

10-i through 10-ii

10-1 through 10-3

4. RESCISSION: VHA Circular 10-91-107.

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Under Secretary for Health

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RESCISSIONS

The following material is rescinded:

COMPLETE RESCISSIONS

a. Manuals

M-2, part VII, dated May 10, 1955, and changes 1 through 25
M-2, part VII, dated December 5, 1977, and changes 1 through 8

b. Interim Issues

10-75-2
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10-73-161
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RESCISSIONS

The following material is rescinded:

Circulars/Directives

10-91-107

CHAPTER 10. INSPECTION OF CONTROLLED SUBSTANCES

10.01 POLICY

It is VA (Department of Veterans Affairs) policy that a Controlled Substance Inspection Program be implemented at all VA medical centers and clinics.

10.02 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) Schedule 1308.12, Schedule III 1308.13, Schedule IV 1308.14, and Schedule V 1308.15.

b. Inspection of wards and clinics will be conducted in accordance with VHA Manual M-2, part I, chapter 2.

(1) The inventory and inspection of ward and clinic Schedule II and III narcotics, and any other controlled substances that require perpetual inventory to be maintained at the ward or clinic level, 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 facility Director, the accuracy of the records and inventory of the controlled substances 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.

c. Monthly inventory and inspection of pharmacy stock, including outdated stock, and records will be made in the presence of the Chief, Pharmacy Service, or a designee. All stock of Schedule II and III narcotic, and bulk stock of III non-narcotic, IV and V, will be included in the monthly inventory inspection. All excess, outdated, unusable, returned controlled substances must be inspected monthly and destroyed at least quarterly. The inspecting official will date and sign VA Form 10-2320, Schedule II, Schedule III Narcotics and Alcohol Register, for each drug preparation at the time of the inspection, certifying the accuracy of the records.

10.03 RESPONSIBILITY

a. 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 controlled substances to ensure safety and control of stocks.

Administration Record, 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 controlled substance stocks and records to confirm that all records and stocks are available for inspection. The inactive VA Form 10-2638, is to be returned to the pharmacy since the last inspection will also be available to the inspecting official. All automatic replenishment records for controlled substances will be provided, as requested.

10.04 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 facility Director.

a. At the smaller facilities, three or four inspectors should be trained and appointed.

b. 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.

10.05 FREQUENCY

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

10.06 AREAS

Areas to be inspected are pharmacy, wards, clinics, laboratories, and all other areas of end use having Schedule II and III narcotics and any other controlled substances drug stock that requires perpetual inventory to be maintained at the ward or clinic level.

a. In cases of inaccuracy in balance of records, the inspecting official(s) will report the discrepancy to the accountable official (i.e., Chief, Pharmacy Service, Head Nurse) who will determine the cause.

b. A report of findings will be made to the facility Director, who will take indicated corrective action.

NOTE: In any suspected theft, diversion or suspicious loss, the procedures outlined in chapter 5, paragraph 5.08 will be followed.

10.07 PHYSICAL INVENTORY OF PHARMACY

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The physical inventory and inspection of pharmacy stocks, including outdated stock, and records (VA Forms 10-2320, 10-2638, and 10-2577F, Security Prescription Form) will be conducted in the presence of the Chief of Pharmacy Service, or the designee.

a. The inspecting official will compare entries on the voucher copies furnished to them by A&MM (Acquisition and Materiel Management) 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.

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b. The inspecting official(s) will date and sign VA Form 10-2320 for each drug or preparation at the time of inspection after:

- (1) Taking a physical inventory;
- (2) Reviewing the receiving and dispensing records;
- (3) Checking calculations; and
- (4) Certifying the accuracy of the record.

10.08 CFR

Current copies of 21 CFR Part 1300 must be available in the office of each Chief, Pharmacy Service and Chief, A&MM Service.

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