

## CHAPTER 17

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### PHARMACEUTICAL SERVICES

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#### 17.A. Pharmaceutical Services

Pharmaceutical services shall be conducted in accordance with currently accepted professional standards of practice and in accordance with all applicable laws and regulations.

Facilities shall develop policies and procedures for the prescribing (including standing orders), obtaining, dispensing, administering, controlling, storing, and disposing of all drugs and biologicals with the advice of a staff pharmacist or a consultant pharmacist and approved by the professional policy group.

#### 17.B. Definitions

17.B.1. Adverse Drug Reaction - is any undesired or unintended effect of a medication, to include:

- a. Hypersensitivity or allergic reactions: a reaction due to a patient's immune response,
- b. Idiosyncrasy: a susceptibility or sensitivity peculiar to a rare phenotype (extreme sensitivity to low doses),
- c. Toxicity: a "poisoning" due to overdosage or accumulation,
- d. Side Effect: an undesired pharmacologic effect which is predictable.

17.B.2. Psychoactive Drugs or Agents - As defined in medical literature, are medications subdivided into five (5) therapeutic classes:

- a. Long-lasting Benzodiazepine drugs;
- b. Benzodiazepine or other anxiolytic sedative drugs;
- c. Drugs for sleep induction;
- d. Antipsychotic drugs;
- e. Antidepressant drugs.

17.B.3. Unnecessary Drug - is any drug that is used in excessive doses, for excessive periods of time, without adequate monitoring, without an appropriate diagnosis or reason for the drug, used in the presence of adverse reactions which indicate that the drug should be reduced or discontinued entirely, and any combination of the above reasons.

#### 17.C. Supervision of Drugs and Biologicals

17.C.1. Each facility shall have a State licensed Pharmacist as a consultant.

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#### 17.C.2. Responsibilities of the Pharmacist Consultant:

- a. Assists with the development of written policies and procedures for pharmaceutical services.
- b. Reviews medication storage areas for, but not limited to, labeling, storage, ventilation, humidity and temperature control, expired medications, security, sanitation and completeness of emergency medications box. (See Chapter 17.I.4.)
- c. Determines that drug records are in order and that an account of controlled drugs is maintained and reconciled.
- d. Monitors adherence to stop order and standing order policies.
- e. Evaluates staff performance in carrying out pharmaceutical policies and procedures.
- f. Reviews the drug regimen of each resident monthly and as needed, including monitoring for unnecessary drugs.
- g. Provides the professional staff with in-service education and on-going communication regarding drugs and biologicals, including information on drug incompatibilities, new drugs, drug sensitivities, and drug interactions.
- h. Participates in resident care conference as appropriate.
- i. Participates in the Professional Policy Committee and Quality Assurance Committee meetings to review and make recommendations relating to pharmaceutical services.

#### 17.C.3. Reports of the Pharmacist Consultant shall contain:

- a. Documentation in the resident's record that review of the medication regimen has been performed and that issues and irregularities identified have been reported to the Director of Nursing and the attending physician.
- b. A description of all activities, findings and recommendations contained in a report submitted to the Director of Nursing and the Administrator.

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17.D. Handling of Drugs and Biologicals

17.D.1. All medications shall be kept in their original containers unless transfer of the medication is done to another storage container by or under the supervision of a pharmacist or a physician. All pharmaceutical containers having soiled, damaged, incomplete, illegible or makeshift labels shall be returned to the issuing pharmacy for relabeling or shall be destroyed in accordance with 17.D.8. of this section.

17.D.2. Each resident's medication container shall be clearly labeled in accordance with State and Federal law and shall include:

- a. Prescription number;
- b. Resident's full name;
- c. The name, strength and dosage form of the drug;
- d. Current directions for use;
- e. Name of prescribing physician;
- f. Name, address and telephone number of the pharmacy issuing the drug;
- g. Date of issue (latest refill);
- h. Expiration date, not to exceed one (1) year from the date of repackaging or dispensing or the manufacturer's original date, whichever is earlier;
- i. Appropriate accessory and cautionary instructions.

17.D.3. There shall be a physical barrier between medications marked "for external use only" and any medication to be taken internally. There shall also be a physical barrier separating eye medications, ear medications and topical medications.

17.D.4. The telephone number of the Poison Control Center shall be conspicuously posted near the telephone at each nurses station.

17.D.5. All drugs and biologicals shall be stored in locked rooms or compartments, separate from food and laboratory specimens, and under proper temperature control in accordance with United States Pharmacopeia standards:

- a. Refrigeration: 36-46 degrees Fahrenheit
- b. Cool 46-59 degrees Fahrenheit
- c. Controlled Room Temperature 59-86 degrees Fahrenheit

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17.D.6. Medications which have an expiration date that has been exceeded shall be removed from use and properly disposed of, according to requirements (17.D.8.).

17.D.7. All prescribed medicines are the property of the resident. Upon discharge of a living resident from a licensed facility, the prescribed medicine, including controlled drugs or substances may be released with the resident, but only upon written authorization of the resident's physician. Each drug release will be documented in the resident's record. Subsequent to discharge, unclaimed medications shall be retained no longer than ninety (90) days.

#### 17.D.8. Disposition of Medications

- a. All prescribed medications, other than Schedule II controlled substances, shall be destroyed by the Director of Nursing Service or a designee, and shall be witnessed by a licensed member of the nursing staff.
- b. The destruction shall be conducted in such a manner as to prevent any persons from being able to use, administer, sell or give away the medication.
- c. Individual unit doses, other than Schedule II through V controlled substances must be returned to the pharmacist and any credit or rebate made to person(s) who originally paid for the medication.
- d. Amounts destroyed or returned to the pharmacy shall be recorded on the resident's record with the signature of two (2) witnesses.
- e. Following the death of the resident, medications shall be removed from circulation within seventy-two (72) hours.
- f. Schedule II controlled substances shall be disposed of as outlined in Section 17.F.2. of this Chapter.

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17.D.9. Licensed facilities may stock in bulk supply those items and drugs regularly available at a pharmacy without prescription.

#### 17.D.10. Reporting of Tampered With or Stolen Drugs

The Department and the Attorney General shall be notified verbally within seventy-two (72) hours when there is suspicion that a medication has been tampered with or stolen. A written report shall also be submitted by the facility to both agencies.

17.D.11. A record shall be maintained, in which the following information shall be available for all prescription medications received in the facility:

- a. Name of resident for whom received;
- b. Name of pharmacy;
- c. Prescription number;
- d. Name of drug and strength;
- e. Amount of medication received;
- f. Date received;
- g. Signature of licensed person receiving the medication.

17.D.12. All resident Schedule II controlled substances received in the facility shall be listed as received in a bound book from which no pages shall be removed

17.D.13. A separate emergency supply inventory, which is the property of the provider pharmacy, shall also be maintained with the following record requirements:

Receiving:

- a. Date received
- b. Name of the nurse receiving
- c. Name, strength and dosage form of the medication
- d. Amount received

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- a. Date used
- b. Nurse administering
- c. Patient's name
- d. Amount used
- e. Amount remaining

These records shall be duplicated and kept as a permanent part of the facility records. The originals remain the property of the pharmacy, as does the medication.

17.D.14. A medication supply shall not be maintained by a resident, unless requested by the resident and specifically authorized by the resident's physician and the multidisciplinary team.

#### 17.E. Administration

17.E.1. Medications shall be administered as prescribed and according to a clearly defined procedural system and reconciled with the physician's orders on a regular basis.

#### 17.E.2. Orders for Medication

a. All medications administered to residents shall be ordered in writing by the resident's physician or authorized designee. Oral orders for medications shall be accepted only by a licensed nurse or pharmacist, immediately reduced to writing, signed by the person accepting the order and countersigned by the attending physician within five (5) business days.

b. Medications not specifically limited as to time or number of doses, when ordered, shall be automatically stopped in accordance with written stop order policy approved by the physician or physicians responsible for advising the facility on its written policies. The resident's physician shall be notified prior to any discontinuance of medication.

c. Orders concerning medications and treatments shall be in writing, signed and dated by a physician and shall be in effect for the time specified by the physician, but not to exceed a period of sixty (60) days. A grace period of ten (10) days may be allowed for the resident whose condition during this period of time did not require a physician's visit.

d. Orders for Schedule II controlled substances shall be in effect for no longer than one (1) week, unless there are specific written orders to the contrary, but in no case shall the order be in effect for a period of more than thirty (30) days without a reorder.

#### 17.E.3. Personnel Administering Medication

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- a. All medications shall be administered by medical and nursing personnel in accordance with the Nurse Practice Act of Maine and applicable law.
- b. All medications shall be administered by licensed medical or nursing personnel, Certified Nursing Assistant/Medications, or other individuals authorized by law who have been issued a certificate indicating completion of an advanced training program including the administration of oral medications as approved by the Maine State Board of Nursing.
- c. Medications which are prescribed to be given as needed must only be administered after an evaluation of the resident by a licensed nurse or physician.
- d. Medications shall be administered as soon as possible after doses are prepared by the same person who prepared the medication for administration.

#### 17.E.4. Medication Identification

The facility must have an organized system for drug administration that identifies each drug up to the point of administration.

#### 17.E.5. Resident Identification

There shall be provision for assuring proper identification of residents by all personnel administering medications.

#### 17.E.6. Self-Administration of Medications

An individual may self-administer medications if the multidisciplinary team has determined that the practice is safe, and with the written permission of the resident's attending physician.

#### 17.F. Control of Narcotics, Barbiturates and Other Controlled Substances

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#### 17.F.1 Policies and Procedures

- a. All facilities shall comply with State and Federal regulations governing narcotics and those drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, and any amendments thereto.
- b. For purposes of this section, narcotics, barbiturates and other controlled substances shall include any substance listed under the Federal Uniform Controlled Substance Act, Sections 1 through 5.
- c. All Schedule II controlled substances, including the emergency supply, received in the facility shall be recorded in a bound drug book as specified in this Chapter. Whenever a container of Schedule II controlled substances has been used up, as evidenced by the record required in this Chapter, it shall be noted in the bound drug order book by signature and date that the supply is depleted.
- d. For all substances listed in Schedule II as above, there shall be an individual narcotic sheet on which shall be recorded the name of the resident receiving the substance, prescription number, the name, date, strength, dosage, and method of administration, the name of the prescribing physician, the signature of the nurse administering it and the balance on hand. This record shall be filed in the individual resident's record upon completion.
- e. The emergency supply inventory shall name the resident for whom the controlled substance was issued, the name of the physician, and the date issued, signed by the nurse issuing the medication and the nurse receiving the medication.
- f. The count of Schedule II controlled substances, to include the emergency supply, shall be recorded and signed at the change of each shift by two people qualified to administer medications, one of whom shall be a licensed nurse.
- g. All Schedule II controlled substances, including the emergency supply, shall be stored under double lock, in a locked box attached to the wall or shelf or locked cabinet within the medication cabinet or cart, or an approved double locked cabinet attached to the wall.
- h. Policies shall be developed relative to the accounting of controlled substances other than Schedule II.

#### 17.F.2. Handling of Unused Schedule II Controlled Substances

- a. The Director of Nursing Services, or a designee, shall list all such unused substances, tape the cap or cover with tamper evident seals and keep the same in a secure, double-locked area, apart from all other drugs. The drugs shall be accessible only to the Director of Nursing or designee.
- b. A current inventory of these substances shall be maintained and recorded in a monthly inventory recorded by the Director of Nursing and one other licensed nurse. These inventories must be maintained for a period of at least five (5) years or as required under Federal/State statutes.

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c. Prior to the destruction of these substances by the authorized person, the inventory shall be verified by that person. Notation shall be made of the destruction, date and signed by all authorized individuals.

d. Disposal of such substances shall occur by incineration or by flushing into the sewage system and shall be made in the presence of a representative from the Department, a Maine licensed pharmacist, a member of the Board of Pharmacy who is a licensed pharmacist, or Federal Drug Enforcement Agency agent. At least one party must be a disinterested party. For the purposes of this section, a disinterested party shall be considered to be either a nurse who was not the last nurse to inventory the discarded item or a pharmacist who is not affiliated with the provider who dispensed the drug.

e. For Schedule II controlled substances, notation of such destruction shall be made on the inventory list required in 17.F.2.b. For Schedule II substances, notation of such destruction shall also be made on the residents individual Schedule II controlled drug sheet, signed and dated by the person who disposed of the drug and the authorized person witnessing the disposition. For Schedule II substances, notation of such destruction shall be made in the bound book required in Chapter 17.F.1.c.

#### 17.G. Recording of Medications

##### 17.G.1. Records of Administration

A record shall be kept of all drugs and medications administered, including name of drug, dose form, dosage, and time given. This shall be promptly recorded on the record of medications and treatment, initialed by the administering individual, with the full name of the individual written somewhere on such record. The need for and response to medications administered which were prescribed to be given as needed shall be documented on the medication or clinical record.

##### 17.G.2. Record of Time Started, Given or Discontinued

Entries shall be made on the medication records to indicate whenever medications are started, given, or discontinued.

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#### 17.H. Reporting of Medication Errors and Adverse Reactions

##### 17.H.1. Reports to Physician

Medication errors and adverse reactions shall be immediately reported to the resident's physician. Medication errors include omissions, as well as errors of commission. Adverse reactions shall also be reported to the pharmacist consultant and pharmacy.

##### 17.H.2. Clinical Records

An entry of the error and/or adverse reaction shall be made in the resident clinical record.

##### 17.H.3. Incident Reports

There shall be an incident report made out for each medication error and/or adverse reaction. These reports shall be kept together on the premises of the facility, reviewed by the Quality Assurance Committee and be made available for review by representatives of the Department.

#### 17.I. Equipment and Supplies

##### 17.I.1. Medicine Cabinet

A cabinet or medication cart shall be provided for individual prescriptions. The cabinet/cart shall be of sufficient size, properly lighted, and located where easily accessible and locked when not in use. The medicine cabinet/cart shall be equipped with separate cubicles, plainly labeled, or provided with other physical separation for the storage of each resident's prescriptions.

##### 17.I.2. Medicine Measuring Devices

Appropriate measuring devices for the accurate measure of liquid medications shall be provided. If not disposable, these medicine containers shall be returned to the institution's dishwashing unit for processing after each use.

##### 17.I.3. Cabinets for Cleaning Supplies and Poisons

There shall be a separate secure cabinet apart from medicine, drugs, and food, for the storage of all bleaches, detergents, disinfectants, insecticide, and poisons. These shall be clearly labeled.

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#### 17.I.4. Emergency Medication Box

There shall be readily available in a secure area, an emergency medication box approved by the facility's group of professional personnel. All medication shall be in single dose form, if available, and any drug removed from the kit shall be replaced within 24 hours and have a drug prescription to cover replacement of same within 5-7 days. An adequate inventory level shall be maintained to assure that a supply is available.

#### 17.I.5. Reference Material

There shall be, readily available to all staff, current (within two [2] years) medication reference material and up-to-date information for all medications in use in the facility.

#### 17.I.6. First Aid Kit

There shall be a first aid kit which is OSHA approved and equipped as facility policy dictates, readily available at each nurses station.