

# Chapter 246-865 WAC

## PHARMACEUTICAL SERVICES—EXTENDED CARE FACILITY

### WAC

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**WAC 246-865-010 Definitions.** (1) "Board" means the Washington state board of pharmacy.

(2) "Department" means the state department of social and health services.

(3) "Dose" means the amount of drug to be administered at one time.

(4) "Drug facility" means a room or area designed and equipped for drug storage and the preparation of drugs for administration.

(5) "Legend drug" means a drug bearing the legend, "Caution, federal law prohibits dispensing without a prescription."

(6) "Licensed nurse" means either a registered nurse or a licensed practical nurse.

(7) "Licensed practical nurse" means a person duly licensed under the provisions of the licensed practical nurse act of the state of Washington, chapter 18.78 RCW.

(8) "Nursing home" means any home, place or institution licensed as a nursing home under chapter 18.51 RCW.

(9) "Pharmaceutical services committee" means a committee which develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice. The pharmaceutical services committee shall consist of a staff or consultant pharmacist, a physician, the director of nursing or his/her designee and the administrator or his/her designee.

(10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy under the provisions of chapter 18.64 RCW.

(11) "Pharmacy" means a place where the practice of pharmacy is conducted, properly licensed under the provisions of chapter 18.64 RCW by the Washington state board of pharmacy.

(12) "Practitioner" means a physician under chapter 18.71 RCW; and osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW; a dentist under chapter 18.32 RCW; a podiatrist under chapter 18.22 RCW; an osteopathic physician's assistant under chapter 18.57A RCW when authorized by the committee of osteopathic commissioners; a physician's assistant under chapter 18.71A RCW when authorized by the board of medical examiners; a registered nurse when authorized by the board of nursing under chapter 18.88 RCW, or a pharmacist under chapter 18.64 RCW.

(13) "Registered nurse" means a person duly licensed under the provisions of the law regulating the practice of registered nursing in the state of Washington, chapter 18.88 RCW.

(14) "Unit-dose" means the ordered amount of a drug in an individually sealed package and in a dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

(15) "Unit-dose drug distribution system" means a system of drug dispensing and control that is characterized by the dispensing of the majority of drugs in unit doses, ready to administer form, and for most drugs, not more than a 48-hour supply of doses is available at the residential care unit at any time.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-865-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), § 360-13-045, filed 9/2/87. Statutory Authority: RCW 18.64.005(11). WSR 81-06-077 (Order 158), § 360-13-045, filed 3/4/81; Order 121, § 360-13-045, filed 8/8/74.]

**WAC 246-865-020 Promulgation.** In the interests of protecting public health the Washington state board of pharmacy shall hereby allow the use of an emergency drug kit in any nursing home holding a valid Washington state nursing home license. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall at all times remain under the ownership of the supplying pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-865-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 81-10-027 (Order 159), § 360-13-010, filed 4/28/81; Order 104, § 360-13-010, filed 12/5/69; Order 50 (part), filed 3/28/67.]

**WAC 246-865-030 Emergency kit.** (1) The contents and quantity of drugs and supplies in the emergency kit shall be determined by the pharmaceutical services committee as defined in WAC 246-865-010(9) which shall consider the number of residents to be served and their potential need for emergency medications.

(2) A copy of the approved list of contents shall be conspicuously posted on or near the kit.

(3) The emergency kit shall be used only for bonafide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner.

(4) Records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the nursing home and the supplying pharmacy.

(5) The pharmaceutical services committee shall be responsible for ensuring proper storage, security and accountability of the emergency kit

(a) The emergency kit shall be stored in a locked area or be locked itself;

(b) Emergency kit drugs shall be accessible only to licensed nurses as defined in WAC 246-865-010(6).

(6) The contents of the emergency kit, the approved list of contents, and all related records shall be made freely available and open for inspection to representatives of the board of pharmacy and the department.

[Statutory Authority: RCW 18.64.005, WSR 92-12-035 (Order 277B), § 246-865-030, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW, WSR 91-18-057 (Order 191B), recodified as § 246-865-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11), WSR 81-06-077 (Order 158), § 360-13-020, filed 3/4/81; Order 104, § 360-13-020, filed 12/5/69; Order 50, subsection 1-12, filed 3/28/67.]

**WAC 246-865-040 Supplemental dose kits.** (1) In addition to an emergency kit, each institution holding a valid Washington state nursing home license, and which employs a unit dose drug distribution system, may maintain a supplemental dose kit for supplemental nonemergency drug therapy if the necessary drug is not available from the pharmacy in a timely manner.

(2) The pharmaceutical services committee shall determine the quantities of drugs in the supplemental dose kit in light of the number of residents in the facility and their potential needs for supplemental doses.

(3) The supplemental dose kit shall remain the property of the supplying pharmacy.

(4) The supplying pharmacy and the facility's pharmaceutical services committee shall be responsible for proper storage, security and accountability of the kit.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW, WSR 91-18-057 (Order 191B), recodified as § 246-865-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11), WSR 81-06-077 (Order 158), § 360-13-030, filed 3/4/81; Order 114, § 360-13-030, filed 6/28/73.]

**WAC 246-865-050 Drug facilities.** (1) There shall be facilities for drug preparation and storage near the nurses' station on each unit.

(2) The drug facilities shall be well illuminated, ventilated and equipped with a work counter, sink with hot and cold running water and drug storage units.

(3) The drug storage units shall provide:

(a) Locked storage for all drugs,

(b) Separately keyed storage for Schedule II and III controlled substances,

(c) Segregated storage of different resident's drugs.

(4) There shall be a refrigerator for storage of thermolabile drugs in the drug facility.

(5) Locks and keys, for drug facilities shall be different from other locks and keys within the nursing home.

(6) Poisons and other nonmedicinal chemical agents in containers bearing a warning label shall be stored in separate locked storage apart from drugs used for medicinal purposes.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW, WSR 91-18-057 (Order 191B), recodified as § 246-865-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11), WSR 81-06-077 (Order 158), § 360-13-055, filed 3/4/81; Order 121, § 360-13-055, filed 8/8/74.]

**WAC 246-865-060 Pharmaceutical services.** (1) Administration of pharmaceutical services.

(a) There shall be provision for timely delivery of drugs and biologicals from a pharmacy so a practitioner's orders for drug therapy can be implemented without undue delay.

(b) Unless the nursing home operates a licensed pharmacy and employs a director of pharmaceutical services, the nursing home shall have a written agreement with one or more licensed pharmacists who provide for pharmaceutical consultant services. The staff pharmacist or consultant pharmacist supervises the entire spectrum of pharmaceutical services in the nursing home.

(c) There shall be a pharmaceutical services committee whose membership includes at least a staff or consultant pharmacist, a physician, the director of nursing or his/her designee, and the administrator or his/her designee. The pharmaceutical services committee develops and maintains written policies and procedures for safe and effective drug therapy, distribution, control, and use which are current and followed in practice.

(d) Reference material regarding the use of medication, adverse reactions, toxicology, and poison control center information shall be available to facility staff.

(e) There shall be procedures established for the reporting and recording of medication errors and adverse drug reactions.

(2) A staff pharmacist or consultant pharmacist shall be responsible for coordinating pharmaceutical services which include:

(a) Provision of pharmaceutical services evaluations and recommendations to the administrative staff.

(b) On-site reviews to ensure that drug handling and utilization procedures are carried out in conformance with recognized standards of practice.

(c) Regularly reviewing each resident's therapy to screen for potential or existing drug therapy problems and documenting recommendations.

(d) Provision of drug information to the nursing home staff and physicians as needed.

(e) Planning and participating in the nursing home staff development program.

(f) Consultation regarding resident care services with other departments.

(3) Security and storage of drugs.

(a) The nursing home shall store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security as defined by regulation and accepted standards of practice.

(b) All drugs shall be stored in locked cabinets, rooms, or carts, and shall be accessible only to personnel licensed to administer or dispense drugs.

(c) Schedule III controlled substances shall be stored apart from other drugs on a separate shelf or in a separate compartment or cabinet, provided, however, Schedule III controlled substances may be stored with Schedule II controlled substances. Schedule III controlled substances can be stored with other drugs when distributed in a unit dose drug distribution system.

(d) Drugs for external use shall be stored apart from drugs for internal use, on a separate shelf or in a separate compartment or cabinet. Any shelf, compartment, or separate

cabinet used for storage of external drugs shall be clearly labeled to indicate it is to be used for external drugs only.

(e) At all times, all keys to drug boxes, cabinets, and rooms shall be carried by persons legally authorized to administer drugs and on duty on the premises.

(f) If a supplemental dose kit within a unit dose drug distribution system is provided it must comply with WAC 246-865-040.

(g) If an emergency kit is provided, it shall comply with Washington state board of pharmacy regulations WAC 246-865-020 and 246-865-030.

(4) Labeling of drugs.

(a) The label for each legend drug which is not dispensed in a unit dose shall have the name and address of the pharmacy from which the drug was dispensed; the prescription number; the physician's name; the resident's full name; the date of issue; the initials of the dispensing pharmacist; the name and strength of the drug; a controlled substances schedule, if any; the amount (e.g., number of tablets or cc's) of the drug dispensed, and the expiration date. In the case of a compounded drug which contains Schedule II or III controlled substances, the quantity of each controlled substance per cc or teaspoonful shall be shown on the label.

(b) In a unit dose drug distribution system, a clear, legible label shall be printed or affixed securely to each unit dose package. Each unit dose drug label shall include: the name, strength and, for each unit dose package, the dosage amount of the drug; the expiration date for any time-dated drug; the lot or control number; and controlled substances schedule number, if any. Each individual drug compartment shall be labeled with the full name of the resident whose drug the compartment contains and the name of the resident's physician.

(c) Nonlegend drugs shall be clearly labeled with at least the patient's name, date of receipt by the facility, as well as display a manufacturer's original label or a pharmacy label if repackaged by the pharmacist. Nonlegend drugs supplied by the extended care facility pursuant to WAC 388-88-050 need not be labeled with the patient's name.

(d) A label on a container of drugs shall not be altered or replaced except by the pharmacist. Drug containers having soiled, damaged, incomplete, or makeshift labels shall be returned to the pharmacy for relabeling or disposal. Drugs in containers having no labels or illegible labels shall be destroyed.

(5) Control and accountability.

(a) The nursing home shall maintain and follow written procedures which provide for the accurate control and accountability of all drugs in the nursing home.

(b) No drugs may be returned from the nursing home to a pharmacy except as provided in paragraph (4)(d) or if the drug is returned in unopened unit dose packages.

(c) Drugs shall be released to a resident upon discharge only on specific written authorization of the attending physician. A receipt containing information sufficient to document the drug's destination, the person who received the drug, and the name and quantity of drugs released shall be entered in the resident's health record.

(d) All of an individual resident's drugs including Schedule III, IV and V controlled substances, that are discontinued by the physician and remain unused, shall be destroyed by a

licensed nurse employee of the nursing home in the presence of a witness within 90 days after having been discontinued, and accurate records of destruction maintained except from drugs which are sealed in unit dose packages.

(e) Outdated, unapproved, contaminated, deteriorated, adulterated, or recalled drugs shall not be available for use in the nursing home.

(f) Except in the case of Schedule II controlled substances and drugs which are sealed in unit dose packages, drugs which remain in the nursing home after the patient has died or been discharged, and drugs in containers with illegible or missing labels, shall be immediately and irretrievably disposed of by a licensed nurse employee in the presence of a witness and proper records maintained of such disposal. Destruction of Schedule II drugs shall be handled in accordance with (6)(g). Unit dose packages may be returned to the pharmacy.

(6) Special requirements for controlled substances.

(a) All Schedule II controlled substances shall be stored in separately keyed and locked secure storage within a drug facility.

(b) Schedule III controlled substances shall be stored apart from other drugs and may be stored on a separate shelf, drawer, or compartment with Schedule II controlled substances.

(c) There shall be a record book for Schedule II and Schedule III controlled substances which shall be a bound book with consecutively numbered pages in which complete records of receipt and withdrawal of Schedule II and III controlled substances are maintained.

(d) At least once each 24 hours, the amount of all Schedule II controlled substances stored in the facility shall be counted by at least two persons who are legally authorized to administer drugs. A similar count shall be made of all Schedule III controlled substances at least weekly. Records of counts shall be entered in the Schedule II and III controlled substances book(s).

(e) When a resident is discharged, a record of release for any Schedule II or III controlled substances released shall be entered on the appropriate page for the given drug in the controlled substances record book.

(f) Any discrepancy in actual count of Schedule II or III controlled substances and the record shall be documented in the Schedule II or III controlled substances books and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy which has not been corrected within seven calendar days shall be reported to the consultant pharmacist and the Washington state board of pharmacy.

(g) Discontinued Schedule II controlled substances and all Schedule II controlled substances which remain after the discharge or death of residents shall:

(i) Be destroyed at the nursing home within 30 days by two of the following individuals: A licensed pharmacist, the director of nursing or a registered nurse designee, and a registered nurse employee of the nursing home with appropriate documentation maintained, or

(ii) Be destroyed at the nursing home by a representative of the Washington state board of pharmacy if so requested by the board or the nursing home.

(h) A nursing home may establish procedures which vary from those paragraphs (6)(a)(g) if they are using a unit dose drug distribution system and if that system provides for the accurate accounting, by the nursing home and the supplying pharmacy, of the receipt and disposition of all Schedule II and III controlled substances.

(7) Drug administration.

(a) Staff shall follow written procedures which provide for the safe handling and administration of drugs to residents.

(i) Drugs shall be administered only by persons licensed to administer drugs.

(ii) The resident shall be identified prior to administration.

(b) All drugs shall be identified up to the point of administration.

(c) Drugs shall be prepared immediately prior to administration and administered by the same person who prepares them except under a unit dose system.

(d) Drug administration shall be documented as soon as possible after the act of administration, and shall include:

(i) Verification of administration

(ii) Reasons for ordered doses not taken

(iii) Reasons for administration of, and response to drugs given on and as needed basis (PRN).

(e) Drug orders shall be received only by a licensed nurse and administered only on the written or verbal order of a practitioner. Verbal orders shall be signed by the prescribing practitioner in a timely manner.

(f) The self-administration of medication program shall provide evidence of:

(i) Assessment of the resident's capabilities

(ii) Instructions for administration

(iii) Monitoring of progress and compliance with orders

(iv) Safe storage of drugs.

[Statutory Authority: RCW 18.64.005. WSR 94-02-077, § 246-865-060, filed 1/5/94, effective 2/5/94; WSR 92-12-035 (Order 277B), § 246-865-060, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-865-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-11-007 (Order 214), § 360-13-066, filed 5/9/88. Statutory Authority: RCW 18.64.005(11). WSR 81-14-055 (Order 161), § 360-13-066, filed 6/30/81.]

**WAC 246-865-070 Provision for continuity of drug therapy for residents.** When a resident of a long term care facility has the opportunity for an unscheduled therapeutic leave that would be precluded by the lack of an available pharmacist to dispense drugs prescribed by an authorized practitioner, a registered nurse designated by the facility and its consultant or staff pharmacist and who agrees to such designation, may provide the resident or a responsible person with up to a 72-hour supply of a prescribed drug or drugs for use during that leave from the resident's previously dispensed package of such drugs. The drugs shall only be provided in accordance with protocols developed by the pharmaceutical services committee and the protocols shall be available for inspection. These protocols shall include the following:

(1) Criteria as to what constitutes an unscheduled therapeutic leave requiring the provision of drugs by the registered nurse;

(2) Procedures for repackaging and labeling the limited supply of previously dispensed drugs by the designated regis-

tered nurse that comply with all state and federal laws concerning the packaging and labeling of drugs;

(3) Provision to assure that none of the medication provided to the resident or responsible person may be returned to the resident's previously dispensed package of such drug or to the facility's stock.

(4) A record-keeping mechanism that will provide for the maintenance of a permanent log that includes the following information:

(a) The name of the person to whom the drug was provided;

(b) The drug and quantity provided;

(c) The date and time that the request for the drug was made;

(d) The date and time that the drug was provided;

(e) The name of the registered nurse that provided the drug;

(f) The conditions or circumstances that precluded a pharmacist from providing the drug.

Refer to WAC 246-839-810 for related regulations on this practice.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-865-070, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-865-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. WSR 83-10-013 (Order 174), § 360-13-100, filed 4/26/83.]