

**Chapter 246-869 WAC
PHARMACY LICENSING**

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WAC

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-869-050	Pharmacy license renewal. [Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-050, 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 § 246-869-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-14-041 (Order 215), § 360-16-025, filed 6/30/88. Statutory Authority: RCW 18.64.043. WSR 84-12-019 (Order 186), § 360-16-025, filed 5/25/84.] Repealed by WSR 98-05-060, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.280.
246-869-095	Facsimile transmission of prescription orders. [Statutory Authority: RCW 18.64.005. WSR 92-14-032 (Order 283B), § 246-869-095, filed 6/23/92, effective 7/24/92.] Repealed by WSR 05-07-108, filed 3/18/05, effective 4/18/05. Statutory Authority: RCW 18.64.005.
246-869-120	Mechanical devices in hospitals. [Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-120, 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 § 246-869-120, filed 8/30/91, effective 9/30/91; Regulation 47, filed 12/1/65.] Repealed by WSR 17-07-027, filed 3/7/17, effective 4/7/17. Statutory Authority: RCW 18.64.005 and chapter 18.64 RCW.
246-869-240	Pharmacist's professional responsibilities. [Statutory Authority: RCW 18.64.005. WSR 92-08-058 (Order 260B), § 246-869-240, filed 3/26/92, effective 4/26/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-240, filed 8/30/91, effective 9/30/91; Order 129, § 360-16-290, filed 7/13/76; Order 127, § 360-16-290, filed 12/1/75.] Repealed by WSR 96-03-016, filed 1/5/96, effective 2/5/96. Statutory Authority: RCW 18.64.005.
246-869-260	Pharmacist supervised sales—General. [Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-260, filed 8/30/91, effective 9/30/91; Regulation 15, filed 3/23/60.] Repealed by WSR 97-20-165, filed 10/1/97, effective 11/1/97. Statutory Authority: RCW 18.64.005.

WAC 246-869-010 Pharmacies' responsibilities. (1) Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances:

(a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-875-040.

(b) National or state emergencies or guidelines affecting availability, usage or supplies of drugs or devices;

(c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine;

(d) Potentially fraudulent prescriptions; or

(e) Unavailability of drug or device despite good faith compliance with WAC 246-869-150.

(2) Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge.

(3) If despite good faith compliance with WAC 246-869-150, the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (1)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include but are not limited to:

(a) Contact the prescriber to address concerns such as those identified in subsection (1)(a) of this section or to obtain authorization to provide a therapeutically equivalent product;

(b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or

(c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner.

(4) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:

(a) Destroy unfilled lawful prescription.

(b) Refuse to return unfilled lawful prescriptions.

(c) Violate a patient's privacy.

(d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.

(e) Intimidate or harass a patient.

[Statutory Authority: RCW 18.64.005, 18.130.050, 18.64.165, 18.130.180. WSR 07-14-025, § 246-869-010, filed 6/25/07, effective 7/26/07.]

WAC 246-869-020 Pharmacies and differential hours. (1) A pharmacy must provide adequate security for its drug supplies and records and in the absence of a pharmacist the pharmacy must be closed and access limited to persons authorized by the pharmacist; for example, janitorial services, inventory services, etc. If a pharmacy is located within a larger mercantile establishment which is open to the public for business at times when a pharmacist is not present then the pharmacy must be enclosed by solid partitions at least seven feet in height, from the floor, which are sufficient to provide adequate security for the pharmacy. In the absence of a pharmacist such pharmacies must be locked and secured so that only persons authorized by the pharmacist can gain access, provided however that employees of the mercantile establishment cannot be authorized to enter the closed pharmacy during those hours that the mercantile establishment is open to the public for business.

(2) All equipment and records referred to in WAC 246-869-180 and all drugs, devices, poisons and other items or products which are re-

stricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area.

(3) Written prescription orders and refill request can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription orders must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drop box" such that the prescription order is stored in the pharmacy area. The times that the pharmacy is open for business must be so displayed that they are prominently visible to the person depositing the prescription orders.

(4) Prescriptions shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place.

(5) No drugs, devices, poisons and other items or products which are restricted to sale either by or under the personal supervision of a pharmacist can be sold or delivered without a pharmacist being present in the pharmacy.

(6) Any pharmacy having hours differing from the remainder of an establishment shall have a separate and distinct telephone number from that business establishment. The phone shall not be answerable in the remainder of the establishment unless all conversations, when the pharmacist is absent, are recorded and played back by the pharmacist.

(7) Oral prescriptions cannot be taken if a pharmacist is not present unless it is taken on a recording which must inform the caller as to the times the pharmacy is open.

(8) A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the times that it is open for business. If a pharmacy is located within a larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being open for business shall be prominently displayed in a permanent manner at the pharmacy area and on or adjacent to the entrance to the mercantile establishment.

(9) Any advertising by the mercantile establishment which makes reference to the pharmacy or those products which are sold only in the pharmacy which in such advertising sets forth the days and hours that the mercantile establishment is open to the public for business must also indicate the days and hours that the pharmacy is open to the public for business.

(10) Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy must notify the board of pharmacy at least thirty days prior to commencing such differential hours. In order to constitute notification the applicant must complete the file forms provided by the board providing the required information. Board inspection and approval must be completed prior to the commencing of such differential hours. Such inspection and approval or disapproval shall be within 10 days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and pharmacy standards under chapter 246-869 WAC.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-020, 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 § 246-869-020, filed 8/30/91, effective 9/30/91; Order 106, § 360-16-005, filed 9/11/70.]

WAC 246-869-030 Pharmacy license notice requirements. (1) Applications for a new pharmacy license must be submitted at least thirty days prior to the next regularly scheduled board meeting and the board shall require the submission of proof of the applicant's identity, and qualifications and such other information as may be necessary to properly evaluate the application, and, at its option, the board may require a personal interview at the next scheduled board meeting.

(2) In case of change of ownership or location of a pharmacy, the original license comes void and must be returned with a new application, as set forth in paragraph (1) above, and the statutorily required fees.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-030, filed 8/30/91, effective 9/30/91; Order 114, § 360-16-011, filed 6/28/73.]

WAC 246-869-040 New pharmacy registration. The commission shall issue a new pharmacy registration to an applicant:

(1) That dispenses or prepares medications and operates with such equipment, facilities, supplies, and pharmaceuticals as are specified by commission laws and appropriate with the scope of services provided;

(2) That completes an inspection without any deficiencies identified or with an approved plan of correction; and

(3) If a pharmacy is in a new or remodeled building, produces evidence of being built or remodeled in accordance with all building, health and fire codes required for the particular area.

[Statutory Authority: Chapter 18.64 RCW and RCW 18.64.005. WSR 18-03-040, § 246-869-040, filed 1/9/18, effective 3/1/18. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-040, filed 8/30/91, effective 9/30/91; Order 130, § 360-16-020, filed 11/10/76; Regulation 10, filed 3/23/60.]

WAC 246-869-060 Employers to require evidence of pharmacist's qualifications. It shall be the duty of every employer to require suitable evidence of qualifications to practice pharmacy before they permit anyone to be in charge, compound or dispense drugs on their premises.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-060, filed 8/30/91, effective 9/30/91; Regulation 19 (part), filed 3/23/60.]

WAC 246-869-070 Responsible manager—Appointment. Every nonlicensed proprietor of one or more pharmacies shall place in charge of each pharmacy a licensed pharmacist who shall be known as the "responsible manager." The nonlicensed proprietor shall immediately report to the state board of pharmacy the name of the "responsible manager," who shall ensure that the pharmacy complies with all the laws, rules and regulations pertaining to the practice of pharmacy. Every portion of the establishment coming under the jurisdiction of the pharmacy

laws shall be under the full and complete control of such responsible manager. A now-licensed proprietor shall at once notify the board of pharmacy of the termination of employment of a responsible manager. Please refer to WAC 246-863-060 for additional information.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-070, 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 § 246-869-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 79-10-007 (Order 151, Resolution No. 9/79), § 360-16-050, filed 9/6/79; Regulation 6, filed 3/23/60.]

WAC 246-869-080 Clinic dispensaries. The clinics of this state shall place their dispensaries in charge of a registered pharmacist, or the dispensing must be done by each prescribing physician in person.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-080, filed 8/30/91, effective 9/30/91; Regulation 9, filed 3/23/60.]

WAC 246-869-090 Prescription transfers. The transfer of original prescription information for a noncontrolled substance legend drug for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(a) Record in the patient medication record system that a copy has been issued.

(b) Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(2) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(a) Write the word "TRANSFER" on the face of the transferred prescription.

(b) Provide all information required to be on the prescription - patient's name and address; prescriber's name and address, and also include:

(i) Date of issuance of original prescription.

(ii) Number of valid refills remaining and date of last refill.

(iii) The pharmacy's name, address, and original prescription number from which the prescription information was transferred.

(iv) Name of transferor pharmacist.

(c) Both the original and transferred prescription must be maintained as if they were original prescriptions.

(d) A transferred prescription may not be refilled after one year from the date the original was issued.

(e) The above subsections apply to the transfer of prescription information for noncontrolled substances. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. 1306.25.

(3) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.

(4) If two or more pharmacies utilize a common electronic database for prescription recordkeeping, prescriptions may be refilled at any of these pharmacies as long as there is provided an audit trail which documents the location of each filling and provisions are made to assure that the number of authorized refills are not exceeded.

[Statutory Authority: RCW 18.64.005 and 69.41.050. WSR 09-19-068, § 246-869-090, filed 9/14/09, effective 10/15/09. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), re-codified as § 246-869-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-23-058 (Order 221), § 360-16-094, filed 11/15/88.]

WAC 246-869-100 Prescription record requirements. (1) Records for the original prescription and refill records shall be maintained on the filled prescription or in a separate record book or patient medication record. Such records must be maintained for a period of at least two years and shall be made available for inspection to representatives of the board of pharmacy.

(2) The pharmacist shall be required to insure that the following information be recorded:

(a) Original prescription—At the time of dispensing, a serial number, date of dispensing, and the initials of the responsible pharmacist shall be placed on the face of the prescription. The patient's address must be readily available to the pharmacist, either from the face of the prescription, a record book, patient medication record, or hospital or clinic record.

(b) Refill prescription authorization—Refills for prescription for legend drugs must be authorized by the prescriber prior to the dispensing of the refill prescription.

(c) Refill prescription—At the time of dispensing, the date of refilling, quantity of the drug (if other than original), the name of authorizing person (if other than original), and the initials of the responsible pharmacist shall be recorded on the back side of the prescription, or in a separate record book or patient medication record.

(d) Prescription refill limitations—No prescription may be refilled for a period longer than one year from the date of the original prescription. "PRN" prescriptions shall expire at the end of one year. Expired prescriptions require authorization before filling. If granted a new prescription shall be written and placed in the files.

(e) Prescription copies—Prescription copies and prescription labels presented for filling must be considered as informational only, and may not be used as the sole document. The prescriber shall be contacted for complete information and authorization. If granted, a new prescription shall be written and placed on file. Copies of prescriptions must be clearly identified as such on the face of the prescription. The transfer of original prescription information is permitted if the provisions of WAC 246-869-090 are met.

(f) Emergency refills—If the prescriber is not available and in the professional judgment of the pharmacist an emergency need for the medication has been demonstrated, the pharmacist may dispense enough medication to last until a prescriber can be contacted - but not to exceed 72 hours' supply. The prescriber shall be promptly notified of the emergency refill.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-100, 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), re-codified as § 246-869-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-22-046, § 360-16-096, filed 10/30/89, effective 11/30/89; WSR 88-23-058 (Order 221), § 360-16-096, filed 11/15/88; Order 131, § 360-16-096, filed 2/4/77; Order 126, § 360-16-096, filed 5/21/75; Order 117, § 360-16-096, filed 11/9/73; Regulation 49, filed 12/1/65.]

WAC 246-869-105 Continuity of care refills in proclaimed emergencies. Notwithstanding WAC 246-869-100 (2)(f), when the governor issues an emergency proclamation for an event which prevents continuity of health care for persons and animals because their prescribed medications are no longer available to them due to the emergency event, pharmacists and pharmacies may provide emergency prescription supplies for medications during the period of the proclaimed emergency as provided below:

(1) An initial supply of up to thirty days of current prescriptions for legend drug (noncontrolled) medications or seven-day supply of current prescriptions for controlled substance medications in Schedules III, IV, and V may be provided to patients under the following conditions:

(a) Presentation of a valid prescription container complete with legible label indicating there are remaining refills, or confirmation of the prescribed medication and available refills by review of the patient's current medical records or pharmacy records or in the professional judgment of the pharmacist; or

(b) If the prescription is expired or has no refills and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a seventy-two hour supply of the prescribed medication as described in WAC 246-869-100 (2)(f) or up to a thirty-day supply of a maintenance medication.

(2) For each medication dispensed under this section, a pharmacist shall:

(a) Document the dispensing as a prescription, noting where the information from subsection (1)(a) of this section was obtained, whether from the prescription container, the patient's prescriber or from the pharmacy records;

(b) Inform the patient's provider and the pharmacy at which the patient obtains his or her medications of the dispensing as soon as possible following the emergency dispensing;

(c) Mark the face of the prescription as an "emergency" prescription.

(3) Nothing in this rule modifies insurers' requirements for coverage and payment for prescribed medications.

[Statutory Authority: RCW 18.64.005 and 18.64.500. WSR 17-01-146, § 246-869-105, filed 12/20/16, effective 12/31/16.]

WAC 246-869-110 Refusal to permit inspection. The refusal to permit an authorized representative of the Washington state board of pharmacy to examine during normal business hours the premises, inven-

tory and/or records relating to drugs of licensed wholesalers, manufacturers, pharmacies and shopkeepers constitutes grounds for the suspension or revocation of the establishment's license and/or that of the pharmacist refusing such requested examination.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-110, filed 8/30/91, effective 9/30/91; Order 109, § 360-16-098, filed 5/23/72; Order 103, § 360-16-098, filed 12/5/69.]

WAC 246-869-130 Return or exchange of drugs. Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

(1) Those drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials in which the pharmacist can readily determine that entry or attempted entry by any means has not been made and which, in the pharmacist's professional judgment, meet the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability may be returned.

(2) Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria;

(a) The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made;

(b) In the pharmacist's professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability;

(c) The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;

(d) The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;

(e) The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable.

(f) If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug.

(3) This rule shall not include items such as orthopedic appliances, crutches, canes, wheelchairs and other similar items unless otherwise prohibited.

(4) Controlled substances shall not be returned to a pharmacy except for destruction in accordance with rules of the drug enforcement administration or the Washington state board of pharmacy.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-130, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 84-12-020 (Order 187), § 360-16-150, filed 5/25/84; Regulation 28, filed 3/23/60.]

WAC 246-869-140 Prescription department—Conversing with pharmacist prohibited. Henceforth the prescription department of every licensed pharmacy in the state of Washington shall be protected against trespass by the lay public. No person shall be permitted to converse with a registered pharmacist while he or she is engaged in compounding a prescription, except nothing in this promulgation shall prevent one pharmacist from consulting with another pharmacist, a physician, a dentist or a veterinary surgeon, regarding the contents or technique connected with or pertaining to, the prescription being compounded.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-140, filed 8/30/91, effective 9/30/91; Regulation 37, filed 11/23/60.]

WAC 246-869-150 Physical standards for pharmacies—Adequate stock. (1) The pharmacy must maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients.

(2) Dated items—All merchandise which has exceeded its expiration date must be removed from stock.

(3) All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration.

(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations.

(5) Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock.

(6) All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-150, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), § 360-16-200, filed 5/21/85; Order 131, § 360-16-200, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 246-869-160 Physical standards for pharmacies—Adequate facilities. (1) The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles).

(2) The prescription department shall be well ventilated. There shall be a constant flow of air through the area.

(3) There shall be a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(4) The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon. (Profile systems are excepted.)

(5) There shall be a sink with hot and cold running water in the prescription compounding area.

(6) There shall be refrigeration facilities with a thermometer in the prescription compounding area for the storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A locked refrigerator in the immediate vicinity of the prescription department will meet the requirements of this paragraph.

(7) The prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items are stored, compounded or dispensed.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-160, filed 8/30/91, effective 9/30/91; Order 131, § 360-16-210, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 246-869-170 Physical standards for pharmacies—Sanitary conditions. (1) The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.

(2) Adequate trash receptacles shall be available, both in the prescription compounding and in the retail areas.

(3) If a restroom is provided, there must be a sink with hot and cold running water, soap and towels, and the toilet must be clean and sanitary.

(4) All equipment must be kept in a clean and orderly manner. That equipment used in the compounding of prescriptions (counting, weighing, measuring, mixing and stirring equipment) must be clean and in good repair.

(5) All professional personnel and staff, while working in the pharmacy, shall keep themselves and their apparel neat and clean.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-170, filed 8/30/91, effective 9/30/91; Order 131, § 360-16-220, filed 2/4/77; Order 51 (part), filed 8/15/67.]

WAC 246-869-180 Physical standards for pharmacies—Adequate equipment. (1) All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(2) All pharmacies will have in their possession one up-to-date copy of the state of Washington statutes and rules governing the prac-

tice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines. Electronic or online versions are acceptable.

(3) All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs.

[Statutory Authority: RCW 18.64.005. WSR 09-08-085, § 246-869-180, filed 3/30/09, effective 4/30/09. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-180, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), § 360-16-230, filed 5/21/85; WSR 84-03-015 (Order 180), § 360-16-230, filed 1/9/84; Order 131, § 360-16-230, filed 2/4/77; Order 118, § 360-16-230, filed 1/2/74; Order 51 (part), filed 8/15/67.]

WAC 246-869-190 Pharmacy inspections and self-inspection worksheets.

(1) Self-inspections. Effective March 1, 2018, the responsible manager, or designee, is required to conduct an annual self-inspection of the pharmacy on the responsible manager self-inspection worksheet(s) provided by the commission. The self-inspection must be completed within the month of March each year.

(a) The responsible manager must sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion.

(b) When a change in responsible manager occurs, the new responsible manager, or designee, shall conduct a self-inspection on the responsible manager self-inspection worksheet(s). The new responsible manager must sign and date the self-inspection worksheet(s) within thirty days of becoming responsible manager, and maintain completed worksheets for two years from the date of completion.

(2) Commission inspection. A pharmacy is subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.

(a) Inspection report.

(i) At the end of the inspection, the commission, or its designee, will conduct an exit meeting with the responsible manager or designee(s), addressing unresolved deficiencies identified during the inspection.

(ii) The commission, or its designee, shall provide a written inspection report to the pharmacy within fourteen calendar days of the exit meeting.

(iii) The inspection report may include unresolved deficiencies identified at the end of a periodic commission inspection, describing the unresolved deficiencies in detail with a reference to all applicable laws.

(b) Plan of correction. A pharmacy must submit a plan of correction to the commission, or its designee, addressing each identified unresolved deficiency.

(i) A "plan of correction" is a proposal devised by the applicant or pharmacy that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(ii) The commission, or its designee, must notify the pharmacy within a time frame set by the commission, whether or not a submitted

plan of correction adequately addresses the unresolved deficiencies identified in the inspection report.

(iii) Implementation of the corrective action is required within the time frames set in the approved plan of correction, and are subject to verification by the commission, or its designee, which may require the pharmacy to submit a progress report(s) attesting to the correction of deficiencies, or a follow-up inspection.

(c) Pharmacies with deficiencies that represent an imminent or immediate risk or threat to public health, safety, and welfare may be subject to summary suspension of the pharmacy license, at the discretion of the commission.

[Statutory Authority: Chapter 18.64 RCW and RCW 18.64.005. WSR 18-03-040, § 246-869-190, filed 1/9/18, effective 3/1/18. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-190, 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 § 246-869-190, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-08-031 (Order 205), § 360-16-235, filed 3/27/87.]

WAC 246-869-200 Poison control. (1) The telephone number of the nearest poison control center shall be readily available.

(2) Each pharmacy shall maintain at least one ounce bottle of Ipecac syrup in stock at all times.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-200, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-08-031 (Order 205), § 360-16-245, filed 3/27/87; Order 120, § 360-16-245, filed 3/11/74.]

WAC 246-869-210 Prescription labeling. To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:

(a) The nature of the drug;

(b) The container in which it was packaged by the manufacturer and the expiration date thereon;

(c) The characteristics of the patient's container, if the drug is repackaged for dispensing;

(d) The expected conditions to which the article may be exposed;

(e) The expected length of time of the course of therapy; and

(f) Any other relevant factors.

The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.

(2) The quantity of drug dispensed, for example the volume or number of dosage units.

(3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-210, 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 § 246-869-210, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.246. WSR 85-06-010 (Order 193), § 360-16-255, filed 2/22/85. Statutory Authority: RCW 18.64.005. WSR 84-22-027 (Order 191), § 360-16-255, filed 11/1/84.]

WAC 246-869-220 Patient counseling required. The purpose of this counseling requirement is to educate the public in the use of drugs and devices dispensed upon a prescription.

(1) The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices.

(2) For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist.

(3) For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription.

(4) This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional authorized to administer medications.

[Statutory Authority: RCW 18.64.005(7). WSR 01-04-055, § 246-869-220, filed 2/5/01, effective 3/8/01. Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-869-220, 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 § 246-869-220, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-04-016 (Order 223), § 360-16-265, filed 1/23/89.]

WAC 246-869-230 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including C.F.R. Part 1700 of Title 16, unless:

(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.

(b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant.

(2) Authorization from the patient to the pharmacist to use a regular container (nonchild-resistant) shall be verified in one of the following ways:

(a) The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant.

(b) The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant.

(c) The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant.

(3) No pharmacist or pharmacy employee may designate himself or herself as the patient's agent.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-230, filed 8/30/91, effective 9/30/91; Order 126, § 360-16-270, filed 5/21/75.]

WAC 246-869-235 Prescription drug repackaging—Definitions. (1)

"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.

(2) "Unit-of-use" means a sufficient quantity of a drug for one normal course of therapy.

(3) "Lot number," "control number" means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which a complete history of the manufacturer, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

(4) "Med-pack" means any package prepared under the immediate supervision of a pharmacist for a specific patient comprising a series of containers and containing one or more prescribed solid oral dosage forms including multifill blister packs.

[Statutory Authority: RCW 18.64.005. WSR 93-01-051 (Order 320B), § 246-869-235, filed 12/10/92, effective 1/10/93.]

WAC 246-869-250 Closing a pharmacy. (1) Whenever a pharmacy

ceases to operate, the owner shall notify the pharmacy board of the pharmacy's closing not later than fifteen days prior to the anticipated date of closing. This notice shall be submitted in writing and shall contain all of the following information:

(a) The date the pharmacy will close;

(b) The names and addresses of the persons who shall have custody of the prescription files, the bulk compounding records, the repackaging records, and the controlled substances inventory records of the pharmacy to be closed;

(c) The names and addresses of any persons who will acquire any of the legend drugs from the pharmacy to be closed, if known at the time the notification is filed.

(2) Not later than 15 days after the pharmacy has closed, the owner shall submit to the pharmacy board the following documents:

(a) The license of the pharmacy that closed; and

(b) A written statement containing the following information;

(i) Confirmation that all legend drugs have been transferred to an authorized person (or persons) or destroyed. If the legend drugs were transferred, the names and addresses of the person(s) to whom they were transferred;

(ii) If controlled substances were transferred, a list of the names and addresses to whom the substances were transferred, the sub-

stances transferred, the amount of each substance transferred, and the date on which the transfer took place;

(iii) Confirmation that the drug enforcement administration (DEA) registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(iv) Confirmation that all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed;

(v) Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-869-250, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.41.240. WSR 83-10-013 (Order 174), § 360-16-300, filed 4/26/83.]

WAC 246-869-255 Customized patient medication packages. The board approves the use of med-pack containers in the dispensing of prescription drugs within the same pharmacy, provided that:

(1) The pharmacy must maintain custody of the original prescription container at the pharmacy;

(2) No more than a thirty-one day supply of drugs is packaged;

(3) The signature of the patient or the patient's agent is obtained for dispensing in a nonchild resistant container;

(4) The container's label bear the following information:

(a) Pharmacy name and address;

(b) Patient's name;

(c) Drug name, strength, quantity;

(d) Directions;

(e) Serial prescription numbers; date

(f) Prescriber's name, and pharmacist's initials.

[Statutory Authority: RCW 18.64.005. WSR 93-01-051 (Order 320B), § 246-869-255, filed 12/10/92, effective 1/10/93.]