Pharmacy Rules Most Pertinent to Business Practice Committee Priority Areas

Summary :

In the past eighteen months, the pharmacy commission has identified area of concern in current pharmacy practice that may affect patient safety. Those include:

Prescription transfer incentives;
Adequate facilities for clinical services;
Ensuring adequate patient counseling;
Prescription Accuracy and CQI processes;
Sufficient Personnel staffing for patient safety;
Metrics and quotas on prescriptions and clinical services.

In addition to these six focuses of business operations already identified from 2012-4, we have identified several exisiting regulations that **may** need attention by the commission regarding pharmacy practice. which include:

WAC 246-869-010

Pharmacies' responsibilities.

Version: April 13, 2015

(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 restricted 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 246-869-110

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, inventory 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 practice 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.

(1) All pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.
(2) Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards.
(3) There shall be three rating classifications:
(a) "Class A" - for inspection scores of 90 to 100;

(b) "Conditional" - for inspection scores of 80 to 89; and,
(c) "Unsatisfactory" - for inspection scores below 80.
(4) Any pharmacy receiving a conditional rating shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.
(5) Any pharmacy receiving an unsatisfactory rating shall have fourteen days to raise its inspection score rating to 90 or better. If upon reinspection after fourteen days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.
(6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.
(7) Noncompliance with the provisions of chapter 18.64A RCW (Pharmacy assistants) and, chapter 246-901 WAC (Pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.
(8) Pharmacies receiving an unsatisfactory rating which represent a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.
[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 substances 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.]

Chapter 246-873 WAC
PHARMACY—HOSPITAL STANDARDS

WAC 246-873-010

Definitions.

For the purpose of these rules and regulations, the following definitions apply:

(1) "Authenticated" or "authentication" means authorization of a written entry in a record by means of a signature which shall include, minimally, first initial, last name, and title.

(2) "Controlled substance" means those drugs, substances or immediate precursors listed in Schedule I through V, chapter 69.50 RCW, State Uniform Controlled Substance Act, as now or hereafter amended.

(3) "Drug" means any product referenced in RCW 18.64.011(3) as now or hereafter amended.

(4) "Drug administration" means an act in which a single dose of a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and regulations governing such acts. The complete act of administration entails removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container) reviewing it with a verified transcription, a direct copy, or the original medical practitioner's orders, giving the individual dose to the proper patient, and properly recording the time and dose given.

(5) "Drug dispensing" means an act entailing the interpretation of an order for a drug or biological and, pursuant to that order, proper selection, measuring, labeling, packaging, and issuance of the drug for a patient or for a service unit of the facility.

(6) "Hospital" means any institution licensed pursuant to chapters 70.41 or 71.12 RCW or designated pursuant to RCW 72.23.020.

(7) "Hospital pharmacy" means that portion of a hospital which is engaged in the manufacture, production, preparation, dispensing, sale, and/or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases; and which is licensed by the state board of pharmacy pursuant to the Washington State Pharmacy Practice Act, chapter 18.64 RCW.

(8) "Immediate supervision" means visual and/or physical proximity that insure adequate safety and controls.

(9) "Investigational drug" means any article which has not been approved for use in the United States, but for which an investigational drug application (IND) has been approved by the FDA.

(10) "Nurse" means a registered nurse or a licensed practical nurse licensed pursuant to chapters 18.88 or 18.78 RCW.

(11) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs in RCW 18.64.011(9).

(12) "Pharmacist" means a person duly licensed by the state board of pharmacy to engage in the practice of pharmacy.

(13) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(14) "Pharmacy Assistant Level A and Level B" means persons certified under chapter 18.64A RCW.

(15) "Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice in the state of Washington.

(16) "Practice of pharmacy" means the definition given in RCW 18.64.011(11) now or

hereafter amended.
(17) "Protocol" means a written set of guidelines.
(18) "Registered nurse" means an individual licensed under the provisions of chapter 18.88 RCW, regulating the practice of registered nursing in the state of Washington.
(19) "Self-administration of drugs" means that a patient administers or takes his/her own drugs from properly labeled containers: Provided, That the facility maintains the responsibility for seeing that the drugs are used correctly and that the patient is responding appropriately.
(20) "Shall" means that compliance with regulation is mandatory.
(21) "Should" means that compliance with a regulation or standard is recommended.
[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), § 360-17-010, filed 5/28/82. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-010, filed 7/29/81.]

WAC 246-873-070

Physical requirements.

(1) Area. The pharmacy facilities shall include:
(a) Appropriate transportation and communications systems for the distribution and control of drugs within the hospital.
(b) Sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies.
(2) In order to meet the medical services' need for drugs throughout the hospital, the pharmacy facilities should include:
(a) Space for the management and clinical functions of the pharmaceutical service.
(b) Space and equipment for the preparation of parenteral admixtures, radiopharmaceuticals, and other sterile compounding and packaging.
(c) Other equipment necessary.
(3) Access to unattended areas. All areas occupied by the hospital pharmacy shall be locked by key or combination in order to prevent access by unauthorized personnel. The director of pharmacy shall designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations.
(4) Drug storage areas. Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
(a) It is the joint responsibility of the director of pharmacy and the director of nursing to ensure that drug handling, storage, and preparation are carried out in conformance with established policies, procedures, and accepted standards.
(b) Locked storage or locked medication carts shall be provided for use on each nursing service area or unit.

(5) Flammable storage. All flammable material shall be stored and handled in accordance with applicable local and state fire regulations, and there shall be written policy and procedures for the destruction of these flammable materials.
[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-873-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 85-11-066 (Order 194), § 360-17-060, filed 5/21/85. Statutory Authority: RCW 18.64.005(11). WSR 81-16-036 (Order 162), § 360-17-060, filed 7/29/81.]

Chapter 246-879 WAC
PHARMACEUTICAL WHOLESALERS
Complete Chapter
WAC 246-879-010
Definitions.
(1) "Full line wholesaler" means any wholesaler authorized by the board to possess and sell legend drugs, controlled substances (additional registration required see WAC 246-879-080) and nonprescription drugs (over-the-counter - OTC see WAC 246-879-070) to a licensed pharmacy or other legally licensed or authorized person.
(2) "Over-the-counter only wholesaler" means any wholesaler authorized by the board to possess and sell nonprescription (OTC) drugs to any outlets licensed for resale.
(3) "Controlled substances wholesaler" means a licensed wholesaler authorized by the board to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.
(4) "Export wholesaler" means any wholesaler authorized by the board to export legend drugs and nonprescription (OTC) drugs to foreign countries.
(5) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
(6) "Blood component" means that part of the blood separated by physical or mechanical means.
(7) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
(8) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, provided that a pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients shall not be considered a manufacturer.
(9) "Prescription drug" means any drug required by state or federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.
(10) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription:
(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(c) The sale, purchase, or trade of blood and blood components intended for transfusion.
(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner.
(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.
(11) "Wholesale distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-010, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-010, filed 3/2/82.]

WAC 246-879-020

Minimum standards for wholesalers.

The following shall constitute minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:
(1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
(d) Be maintained in a clean and orderly condition; and
(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
(2) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of

such drugs or with the requirements in the 22nd edition of the United States Pharmacopeia/National Formulary (USP/NF). United States Pharmacopeia/National Formulary (USP/NF) is available for public inspection at the Office of the State Board of Pharmacy, 1300 Quince St SE, PO Box 47863, Olympia WA 98504-7863.
(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.
(3) Examination of materials.
(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to contents.
(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
(4) Returned, damaged, and outdated prescription drugs.
(a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
(b) Any drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.
(c) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
(5) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies:
(a) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.
(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other governmental agency, including the board of pharmacy;
(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.
(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
(d) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.
(6) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-020, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-020, filed 3/2/82.]

WAC 246-879-030

Inspections.

(1) Inspections shall be performed by representatives of the board of pharmacy to ensure compliance with chapter 246-879 WAC. The following items shall be included in these inspections:
(a) Housekeeping, sanitation, recordkeeping, accountability, security, types of outlets sold to and sources of drugs purchased.
(b) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
(2) Wholesale drug distributors shall permit the board's authorized personnel and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-030, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-

042 (Order 165), § 360-21-030, filed 3/2/82.]

WAC 246-879-040

Records.

(1) Recordkeeping. Wholesale drug distributors shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:
(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
(b) The identity and quantity of the drugs received and distributed or disposed of; and
(c) The dates of receipt and distribution or other disposition of the drugs.
(2) Inventories and records shall be made available for inspection and photocopying by an authorized official of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs.
(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of these rules.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-040, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-040, filed 3/2/82.]

WAC 246-879-050

Security.

(1) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(2) Access from outside the premises shall be kept to a minimum and be well-controlled.
(3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
(4) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
(5) Drug storage areas shall be constructed in such a manner as to prevent illegal entry.
(6) Adequate lighting shall be provided at the outside perimeter of the premises to reduce the possibility of illegal entry.

(7) All applicants for a license as a controlled substances wholesaler must comply with the security requirements as found in 21 C.F.R. 1301.02, 1301.71 through 1301.74 and 1301.90 through 1301.92.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-050, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-050, filed 3/2/82.]

WAC 246-879-060

Unauthorized sales.

No wholesaler distributor shall sell or distribute any prescription drugs or devices except to an individual, corporation, or entity who is authorized by law or regulation to possess such drugs or devices. No wholesaler shall sell any prescription drugs or devices to an ultimate consumer.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-060, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-060, filed 3/2/82.]

WAC 246-879-070

Application for full line wholesaler license and over-the-counter only wholesaler license.

(1) All applications for licensure of a new or relocated wholesaler shall be accompanied by the required fee as set forth in chapter 246-907 WAC.
(2) All license renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (6) of this section.
(3) A change of ownership or location requires a new license.
(4) The license is issued to a person or firm and is nontransferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.
(5) The license fee cannot be prorated.
(6) Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in wholesale distribution of prescription drugs.
(a) Minimum required information for licensure. The board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license.
(i) The name, full business address, and telephone number of the licensee;

(ii) All trade or business names used by the licensee;
(iii) Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;
(iv) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
(v) The name(s) of the owner and/or operator of the licensee, including:
(A) If a person, the name of the person;
(B) If a partnership, the name of each partner, and the name of the partnership;
(C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;
(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.
(vi) When operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the board.
(vii) Change in any information required by this section shall be submitted to the board within thirty days after such change.
(b) Minimum qualifications. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:
(i) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;
(ii) Any felony convictions of the applicant under federal, state, or local laws;
(iii) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
(iv) Any false or fraudulent material furnished by the applicant in any application made in connection with drug manufacturing or distribution;
(v) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
(vi) Compliance with licensing requirements under previously granted licenses, if any;
(vii) Compliance with requirements to maintain and/or make available to the board, federal, state, or local enforcement officials those records required to be maintained by wholesale drug distributors; and
(viii) Any other factors or qualifications the board considers relevant to and consistent with public health and safety.
(c) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based on factors and qualifications that are directly related to the protection of the public health and safety.
(d) Personnel. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.
[Statutory Authority: RCW 43.70.280. WSR 98-05-060, § 246-879-070, filed 2/13/98,

effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-070, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-070, filed 3/2/82.]

WAC 246-879-080

Application for controlled substance wholesaler license.

Wholesale drug distributors that deal in controlled substances shall register with the board and with the Drug Enforcement Administration (DEA), and shall comply with applicable state, local, and DEA regulations.
(1) He/she must be licensed as a full line wholesaler.
(2) He/she must meet all security requirements as set forth in WAC 246-879-050.
(3) He/she must meet additional requirements for registration and fees as set forth in chapter 246-907 WAC.
[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-080, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-080, filed 3/2/82.]

WAC 246-879-090

Export wholesaler.

(1) Upon application the board may issue a wholesaler license for the primary business of exporting drugs to foreign countries.
(2) Such license authorizes the holder to export non-controlled drugs to persons in a foreign jurisdiction that have legitimate reasons to possess such drugs.
(3) Letters from consulate of the country to which drugs are exported should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the board upon its request.
(4) Records to be kept by export wholesaler:
(a) Complete description of drug, including, name, quantity, strength, and dosage unit.
(b) Name and address of purchaser.
(c) Name and address of consignee in the country of destination.
(d) Name and address of forwarding agent.
(e) Proposed export date.
(f) Shippers involved and methods of shipment.
(5) The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.
[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order

191B), recodified as § 246-879-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-090, filed 3/2/82.]

WAC 246-879-100

Salvaging and reprocessing companies.

Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to prescription drug product salvaging or reprocessing, including this chapter.

[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-100, filed 7/14/92, effective 8/14/92.]

WAC 246-879-110

Violations and penalties.

The board shall have the authority to suspend or revoke any licenses granted under this chapter upon conviction of violations of the federal, state, or local drug laws or rules. Before any license may be suspended or revoked, a wholesale distributor shall have a right to prior notice and a hearing pursuant to the Administrative Procedure Act, chapter 34.05 RCW.

[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-110, filed 7/14/92, effective 8/14/92.]

WAC 246-879-120

Reciprocity.

A wholesale distributor licensed in another state may be licensed in this state upon submission of the fee required in chapter 246-907 WAC and submission of information compiled by the National Association of Boards of Pharmacy (NABP) Clearinghouse demonstrating that the license is not, and has not been, the subject of adverse license action.

[Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-120, filed 7/14/92, effective 8/14/92.]

PHARMACEUTICAL SERVICES—EXTENDED CARE FACILITY

Complete Chapter

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 administer 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 registered 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.]

WAC 246-869-080 No agency filings affecting this section since 2003

Clinic dispensaries.
The clinics of this state shall place their dispensaries in charge of a registered pharmacist, or the dispe
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.]

-Chapter 246-881 WAC
PHARMACY—PRESCRIPTION DRUG PRICE ADVERTISING

WAC 246-881-010
Drug price advertising defined.
Drug price advertising is the dissemination of non-promotional information pertaining to the prices of legend or prescription drugs.
[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-881-010, filed 8/30/91, effective 9/30/91; Order 124, § 360-23-010, filed 10/31/74; Order 120, § 360-23-010, filed 3/11/74.]

WAC 246-881-020
Drug price advertising conditions.
A pharmacy may advertise legend or prescription drug prices provided:
(1) The advertising complies with all state and federal laws, including regulations of the United States Food and Drug Administration and the Washington State Consumer Protection Act, chapter 19.86 RCW.
(2) The advertising is solely directed towards providing consumers with drug price information and does not promote the use of a prescription drug or drugs to the public.
(3) The drug price advertising shall contain all the following information for all drug products or brand names used in the advertisement:
(a) The proprietary name of the drug product advertised, if any,
(b) The generic name of the drug product advertised, if any,
(c) The strength of the drug product advertised. If the drug product advertised contains more than one active ingredient and a relevant strength can be associated with it without indicating each active ingredient, the generic name and quantity of each active ingredient is not required.
(d) The dosage form of the drug product advertised, and
(e) The price charged for a specified quantity of the drug product.
(4) Advertising of any generic drug that in any way compares a generic drug to a brand name drug may not in any manner imply that the brand name drug is the product offered for sale.
[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-881-020, 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), § 360-23-020, filed 9/6/79; Order 124, § 360-23-020, filed 10/31/74; Order 120, § 360-23-020, filed 3/11/74.]

WAC 246-881-030
Prohibition on advertising controlled substances.

No person, partnership, corporation, association or agency shall advertise controlled substances for sale to the general public in any manner that promotes or tends to promote the use or abuse of those drugs. Controlled substances shall not be physically displayed to the public.
[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-881-030, filed 8/30/91, effective 9/30/91; Order 124, § 360-23-030, filed 10/31/74.]

WAC 246-881-040

Drug price disclosure—Required.

No pharmacy shall refuse to disclose the retail price of a prescription drug upon request by a consumer.
[Statutory Authority: RCW 18.64.005. WSR 96-02-008, § 246-881-040, filed 12/20/95, effective 1/20/96. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-881-040, filed 8/30/91, effective 9/30/91; Order 124, § 360-23-050, filed 10/31/74.]

Chapter 246-904 WAC
HEALTH CARE ENTITIES

WAC 246-904-010

Definition.

Health care entity - an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes any of the following which are not part of another licensed facility, including: Outpatient surgery centers, cardiac care centers, or kidney dialysis centers. It does not include an individual practitioner's office or a multipractitioner clinic.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-010, filed 12/20/96, effective 1/20/97.]

246-904-020

New health care entity licensing.

No health care entity shall be issued a license until the facility has submitted an application along with the applicable fees set forth in WAC 246-907-020 through 246-907-030 and has passed an inspection by a Washington state board of pharmacy investigator. The investigator shall determine if the purchase, ordering, storing, compounding, delivering, dispensing and administration of controlled substances and/or legend drugs complies with all applicable state and federal statutes and regulations. Physical requirements for the areas of a health care entity where drugs are stored, compounded, delivered or dispensed shall comply with WAC 246-873-070.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-020, filed 12/20/96, effective 1/20/97.]

WAC 246-904-030

Pharmacist in charge.

Every health care entity licensed under this chapter shall designate a pharmacist in charge. The pharmacist in charge may be employed in a full-time capacity or as a pharmacist consultant. The pharmacist in charge must be licensed to practice pharmacy in the state of Washington. The pharmacist in charge designated by a health care entity shall have the authority and responsibility to assure that the area(s) within the health care entity where drugs are stored, compounded, delivered or dispensed are operated in compliance with all applicable state and federal statutes and regulations.

It shall be the responsibility of the pharmacist in charge:

(1) To create and implement policy and procedures relating to:

(a) Purchasing, ordering, storing, compounding, delivering, dispensing or administering of controlled substances or legend drugs.

(b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal regulations.

(c) Adequate security of legend drugs and controlled substances.

(d) Controlling access to controlled substances and legend drugs.

(2) To assure that the Washington state board of pharmacy is in possession of all current policies and procedures identified in subsection (1) of this section.

(3) To execute all forms for the purchase and order of legend drugs and controlled substances.

(4) To verify receipt of all legend drugs and controlled substances purchased and ordered by the health care facility.

[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-030, filed 12/20/96, effective 1/20/97.]

WAC 246-904-040

Drug procurement, distribution and control.

The procurement, distribution and control of drugs shall be in accordance with WAC 246-873-080.

[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-040, filed 12/20/96, effective 1/20/97.]

WAC 246-904-050

Dispensing of prescription medications from health care entities.
Drugs dispensed to patients of a health care entity must be dispensed in a manner consistent with the requirements of RCW 18.64.246 through 18.64.247, chapters 69.41 and 69.50 RCW, and WAC 246-869-220 through 246-869-240.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-050, filed 12/20/96, effective 1/20/97.]

WAC 246-904-060

Labeling.

Drugs dispensed to patients of a health care entity must comply with the labeling requirements of WAC 246-869-210.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-060, filed 12/20/96, effective 1/20/97.]

WAC 246-904-070

Records.

To the extent applicable, all prescription records shall be maintained in accordance with WAC 246-869-100 and chapter 246-875 WAC et seq.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-070, filed 12/20/96, effective 1/20/97.]

WAC 246-904-080

Absence of a pharmacist.

Pharmaceutical services shall be available at all times patients are present in the facility. At times when no pharmacist is in the facility, the entity must comply with the requirements of WAC 246-873-050 and 246-873-060.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-080, filed 12/20/96, effective 1/20/97.]

WAC 246-904-090

Administration.

Administration of drugs to patients of a health care entity shall be in accordance with WAC 246-873-090.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-090, filed 12/20/96, effective 1/20/97.]

WAC 246-904-100

Closing.

When a health care entity ceases to do business or to provide pharmaceutical services to patients, the entity shall follow the provisions of WAC 246-869-250.
[Statutory Authority: RCW 18.64.450. WSR 97-02-015, § 246-904-100, filed 12/20/96, effective 1/20/97.]