DIVISION 80

SCHEDULE OF CONTROLLED SUBSTANCES

Registration of Manufacturers, Distributors and Dispensers

Controlled Substances Prescriptions

DIVISION 90

AEROSOL SPRAYS

DIVISION 110

FEES

DIVISION 1

PROCEDURAL RULES

855-001-0000
Notice of Proposed Rule

Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy shall give notice of its intended action as required in ORS 183.335(1):

(1) In a manner established by rule adopted by the Board under ORS183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;

(2) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;

(3) To persons who have requested notice pursuant to ORS183.335(8) at least 28 days before the effective date; and

(4) To persons specified in ORS 183.335(15) at least 49 days before the effective date; and

(5) To persons or organizations the Board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of the proposal; and

(a) Oregon State Pharmacist Association;

(b) Oregon Society of Health System Pharmacists;

(6) To the Associated Press and the Capitol Press Room.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 183.335
Hist.: 1PB 42, f. & ef. 4-6-76; 1PB 54, f. & ef. 12-13-77; 1PB 1-1978, f. & ef. 2-21-78; 1PB 7-1978(Temp), f. & ef. 7-1-78; 1PB 9-1978, f. & ef. 10-23-78; BP 1-2001, f. & cert. ef. 3-5-01; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 1-2005, f. & cert. ef. 2-7-05; BP 1-2007, f. & cert. ef. 6-29-07

855-001-0005
Model Rules of Procedure

The following Model Rules of Procedure promulgated by the Attorney General of the State of Oregon in effect on January 01, 2008, are adopted by the Board by reference. These rules apply to rule making and to the conduct of contested cases, respectively.

(1) OAR 137-001-0005 through 137-001-0100;

(2) OAR 137-003-0000 through 137-003-0700.

[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]
Stat. Auth.: ORS 183.341 & 689.205
Stats. Implemented: ORS 183.341
Hist.: 1PB 25, f. 3-20-72, ef. 4-15-72; 1PB 31, f. 11-20-73, ef. 12-11-73; 1PB 42, f. & ef. 4-6-76; Renumbered from 855-010-0030; 1PB 7-1978(Temp), f. & ef. 7-1-78; 1PB 9-1978, f. & ef. 10-23-78; 1PB 1-1980, f. & ef. 1-21-80; 1PB 3-1981, f. & ef. 12-15-81; PB 2-1987, f. & ef. 3-30-87; PB 5-1988, f. & cert. ef. 10-17-88; PB 4-1992, f. & cert. ef. 8-25-92; PB 1 -1996, f. & cert. ef. 4-5-96; BP 1-2001, f. & cert. ef. 3-5-01; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 5-2004, f. & cert. ef. 10-1-04; BP 13-2006, f. & cert. ef. 12-19-06; BP 3-2008, f. & cert. ef. 7-1-08

855-001-0010
Requiring an Answer to Charges as Part of Notices to Parties in Contested Cases

In addition to the requirements stated in rule 137-003-0505 of the Attorney General's Model Rules of Procedure adopted under OAR 855-001-0005, the notice to parties in contested cases may include a statement that an answer to the assertions or charges will be required, and if so, the consequences of failure to answer may be by enclosing a copy of rule 855-001-0015 with the notice.

Stat. Auth.: ORS 183
Stats. Implemented: ORS 689
Hist.: 1PB 48(Temp), f. & ef. 2-14-77; 1PB 50, f. & ef. 4-20-77; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

855-001-0012
Time For Requesting a Contested Case Hearing

A request for a contested case hearing must be in writing and must be received by the Board within twenty-one days from the date the contested case notice was served.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.:BP 1-2001, f. & cert. ef. 3-5-01

855-001-0015
Hearing Request and Answers: Consequences of Failure to Answer

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

(a) An admission or denial of each factual matter alleged in the notice;

(b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause:

(a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;

(b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;

(c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and

(d) Evidence shall not be taken on any issue not raised in the notice and the answer.

Stat. Auth.: ORS 183
Stats. Implemented:
Hist.: 1PB 48(Temp), f. & ef. 2-14-77; 1PB 50, f. & ef. 4-20-77

855-001-0016
Filing Exceptions and Argument to the Board

After a proposed order has been served on a party, the Board shall notify the party when written exceptions must be filed to be considered by the Board and the Board shall notify the party when the party may appear before the Board to present argument regarding the proposed order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: BP 1-2001, f. & cert. ef. 3-5-01

855-001-0017
Petition for Reconsideration or Rehearing As Condition for Judicial Review

All parties, including limited parties, must file a petition for reconsideration or rehearing with the Board as a condition for obtaining judicial review of any order of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: BP 1-2001, f. & cert. ef. 3-5-01

855-001-0035
Duty to Cooperate

Every licensee and registrant of the Board shall cooperate with the Board and shall respond fully and truthfully to inquiries from and comply with any requests from the Board, subject only to the exercise of any applicable right or privilege.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689
Hist.: PB 1-1992, f. & cert. ef. 1-31-92; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

855-001-0040
Inspections

(1) The Board or its authorized representative may enter and shall be allowed entry to any drug outlet where drugs are stored, and the premises where the records associated with those drugs are stored, to conduct inspections at reasonable times in a reasonable manner for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept under the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rules including, but not limited to, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each;

(b) Inspecting within reasonable limits and a reasonable manner all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and labeling found at the drug outlet;

(c) Making a physical inventory of all drugs on hand at the premises;

(d) Collecting samples of drugs or ingredients;

(e) Checking of records and information on distribution of drugs by the registrants as they relate to total distribution of the registrant;

(f) All other things appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rules.

(2) The inspections hereunder may be conducted in connection with applications for initial or renewal registration or modification or amendment thereof and at such other times where the Board or its authorized representative determines that there is reasonable basis for concluding that inspection is necessitated in order to ensure that there is compliance with the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rules.

(3) Refusal to allow inspection is grounds for denial, suspension, or revocation of a registration.

Stat. Auth.: ORS 475.125 & ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; Renumbered from 855-080-0060, BP 1-2007, f. & cert. ef. 6-29-07

DIVISION 6

DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) "Certified Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the pharmacist are not considered pharmacy technicians.

(2) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one pharmacist and one practitioner; or

(b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.

(3) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the pharmacist and the patient, in the course of professional practice; or

(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; or

(d) As a component of a Shared Pharmacy Service agreement as defined in section (21) of this rule.

(4) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(5) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.

(6) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(7) "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(8) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.

(9) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of anon-prescription drug or commercially packaged legend drug or device.

(10) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.

(11) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

(12) "Nationally Certified Exam" means an exam that is approved by the Board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.

(13) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(14) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:

(a) The creation and retention of accurate and complete patient records;

(b) Assuming authority and responsibility for product selection of drugs and devices;

(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the general public;

(d) Maintaining confidentiality of patient information.

(15) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.

(16) Participation in Drug Selection and Drug Utilization Review:

(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.

(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:

(A) Over-utilization or under-utilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug dosage;

(F) Incorrect duration of treatment;

(G) Drug-allergy interactions; and

(H) Clinical drug abuse or misuse.

(17) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:

(a) Cure of a disease;

(b) Elimination or reduction of a patient's symptomatology;

(c) Arrest or slowing of a disease process; or

(d) Prevention of a disease or symptomatology.

(18) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the specialized education program pursuant to OAR855-025-0010.

(19) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.

(20) "Prohibited conduct" means conduct by a licensee that:

(a) Constitutes a criminal act against a patient or client; or

(b) Constitutes a criminal act that creates a risk of harm to a patient or client.

(21) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:

(a) Assure retention of their purity and potency;

(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;

(c) Assure security and minimize the risk of their loss through accident or theft;

(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;

(e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.

(22) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.

(23) "Shared Pharmacy Service" means a written agreement, that has been approved in writing by the board, that exists for the processing by a pharmacy of a request from another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a prescription or a drug order, or to perform processing functions including but not limited to:

(a) Dispensing;

(b) Drug utilization review;

(c) Claims adjudication;

(d) Refill authorizations;

(e) Compounding; and

(f) Therapeutic interventions.

(24) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as pharmacy technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or

(b) A structured program approved by the board and designed to educate pharmacy technicians in one or more specific issues of patient health and safety that is offered by:

(A) An organization recognized by the board as representing pharmacists or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

(C) A trade association recognized by the board as representing pharmacies.

(25) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified pharmacy technician's action.

(26) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.

(27) "Unprofessional conduct" means conduct unbecoming a licensee or detrimental to the best interests of the public, including conduct contrary to recognized standards of ethics of pharmacy or conduct that endangers the health, safety or welfare of a patient or client. Unprofessional conduct includes but is not limited to:

(a) Fraud or misrepresentation in dealings relating to pharmacy practice with:

(A) Customers, patients or the public;

(B) Practitioners authorized to prescribe drugs, medications or devices;

(C) Insurance companies;

(D) Wholesalers, manufactures or distributors of drugs, medications or devices;

(E) Health care facilities;

(F) Government agencies; or

(G) Drug outlets.

(b) Illegal use of drugs, medications or devices without a practitioner's prescription, or otherwise contrary to federal or state law or regulation;

(c) Any use of intoxicants, drugs or controlled substances that endangers or could endanger the licensee or others;

(d) Theft of drugs, medications or devices, or theft of any other property or services under circumstances which bear a demonstrable relationship to the practice of pharmacy;

(e) Dispensing a drug, medication or device where the pharmacist knows or should know due to the apparent circumstances that the purported prescription is bogus or that the prescription is issued for other than a legitimate medical purpose, including circumstances such as:

(A) Type of drug prescribed;

(B) Amount prescribed; or

(C) When prescribed out of context of dose.

(f) Any act or practice relating to the practice of pharmacy that is prohibited by state or federal law or regulation;

(g) The disclosure of confidential information in violation of Board rule;

(h) Engaging in collaborative drug therapy management in violation of ORS Chapter 689 and the rules of the Board;

(i) Authorizing or permitting any person to practice pharmacy in violation of the Oregon Pharmacy Act or the rules of the Board;

(j) Any conduct or practice by a licensee or registrant which the Board determines is contrary to accepted standards of practice; or

(k) Failure to cooperate with the Board pursuant to OAR 855-001-0035.

(28) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified pharmacy technician.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.305, 689.405, OL 2009, Ch. 536
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; PB 2-1988, f. & cert. ef. 5-3-88; PB 2-1989, f. & cert. ef. 1-30-89; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; BP 4-1998, f. & cert. ef. 8-14-98; BP 1-2006, f. & cert. ef. 6-9-06; BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

855-006-0015
Additional Definitions

(1) Electronically Transmitted Prescription:

(a) Where used in this chapter, Electronically Transmitted Prescription (ETP) means a prescription for a drug or medical device issued by a practitioner, who is licensed and authorized to prescribe pursuant to the laws of this state and is acting within the scope of his or her practice, which has been transmitted by an electronic means that may include but is not limited to:

(A) Transmission by facsimile or hand held digital electronic device to a computer or facsimile;

(B) Transmission from a computer to another computer;

(C) Transmission by facsimile to computer; or

(D) Transmission from a computer to facsimile.

(b) ETP does not include an oral prescription that has been reduced to writing by a pharmacist pursuant to OAR 855-041-0085 and does not include prescriptions, or drug or device orders written for inpatient use in a hospital.

(c) For an ETP to be valid, it must contain the name and immediate contact information of the prescriber, and be electronically encrypted or in some manner protected by up-to-date technology from unauthorized access, alteration or use.

(2) Tamper-resistant Prescription:

(a) Where used in this chapter, Tamper-resistant Prescription means a form for the purpose of issuing a hand written or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, produced and formatted to ensure security, integrity and authenticity using currently accepted technologies.

(b) Formatted features may include but are not limited to characteristics such as:

(A) The word "void" appears when photocopies are attempted;

(B) Background ink which reveals attempted alterations;

(C) Heat sensitive ink that changes colors;

(D) Penetrating ink to prevent chemical alterations;

(E) A watermark which cannot be photocopied;

(F) Coin reactive ink that reveals word when rubbed with a coin;

(G) Sequential numbering.

Stat. Auth.: 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2007(Temp), f. & cert. ef. 8-27-07 thru 2-18-08; BP 1-2008, f. & cert. ef. 2-5-08

DIVISION 7

PUBLIC HEALTH EMERGENCY

855-007-0010
Declaration of Emergency

(1) With the exception of OAR 855-007-0060(2)(a) and (b), 855-007-0080(2), 855-007-0080(8)(a) and (b), and 855-007-0120 that are always in effect, the rules in this Division are only effective when:

(a) A State of Emergency or a Public Health Emergency has been declared by the Governor of Oregon under ORS 401.055 or 433.441 through 433.452;

(b) The provisions of any relevant rules in chapter 855 Oregon Administrative Rules have been suspended by the Governor under the authority of ORS 401.065(2);

(c) A signatory to the Pacific Northwest Emergency Management Arrangement (the states of Alaska, Idaho, Oregon, Washington, the Province of British Columbia, and Yukon) has requested assistance during a civil emergency as authorized in Chapter 25 Oregon Laws 2008;

(d) A signatory to the Emergency Management Assistance Compact has requested assistance during a civil emergency as authorized in ORS 401.043;

(e) The President of the United States or another federal official has declared a public health emergency; or

(f) The Governor has authorized the Public Health Director to take the actions described in ORS 431.264.

(2) When these rules are authorized by any one of the actions listed in (1)(a)–(f) they are in effect to the extent necessitated by the scope of the declaration, and control to the extent that they are in conflict with other Divisions of OAR Chapter 855.

Stat. Auth.: ORS 401.043, 401.065, 433.441 & 689.205
Stats. Implemented: 2008 OL Ch. 25, ORS 401.055 & 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 3-2009(Temp), f. & cert. ef. 8-19-09 thru 2-15-10; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0020
Applicability

(1) These rules apply to all persons licensed or registered with the Board under OAR chapter 855 and to any persons acting under the authority of Oregon State Public Health Division or any other state agency, or any local or county health department or emergency manager, during a Declared Emergency or a Public Health Emergency, or to any such person acting in preparation for a Public Health Emergency.

(2) These rules may apply to the whole state of Oregon or only to a county or area included in the declared emergency. They also apply to the activities of any licensee or registrant who is working during a declared emergency in the state or territory of any of the signatories of Pacific Northwest Emergency Management Arrangement or the Emergency Management Assistance Compact.

(3) These rules apply to the dispensing and administration of drugs and vaccines to any person within an area subject to an emergency declaration or to any person who has been displaced from their place of residence even if the place to which they have been displaced has not been included in the emergency declaration.

(4) Insofar as neither the Governor of Oregon nor the Board has the authority to waive any provisions of Federal Law, nothing in these rules that conflicts with the Federal Controlled Substances Act (CSA) or the implementing regulations in 21 CFR, shall apply to federal controlled substances as listed in Division 80 of this chapter of rules, unless an agency of the US Government has waived the appropriate section of the CSA or the implementing regulations in 21 CFR.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: 2008 OL Ch. 25 & ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0030
Definitions

(1) "Administer" has the meaning given that term in ORS 689.005.

(2) "Community Partner" has the meaning given that term in OAR 855-007-0080.

(3) "Dispense" has the meaning given that term in ORS 689.005.

(4) "Distribute" has the meaning given that term in ORS 689.005.

(5) "Drug" in this division of rules, the term "drug" means a drug or vaccine or medical device, or any combination of these terms.

(6) "Emergency" has the meaning given that term in ORS 401.025.

(7) "Emergency Management Assistance Compact" (EMAC) means the compact for mutual assistance that was ratified by Congress and signed by all states, and is codified in ORS 401.043.

(8) "Emergency Prescription" means a record that is created in a pharmacy that records the dispensing of a refill of a drug, or a new or modified drug therapy to a patient in the absence of a valid prescription.

(9) "Health-care provider" means an individual licensed, certified or otherwise authorized or permitted by the laws of this state or another state to administer health-care services within their scope of practice.

(10) "Mobile Pharmacy" means a pharmacy that is located in a vehicle or a trailer.

(11) "Oregon State Public Health Division" (OSPHD) means that division of the Oregon Department of Human Services (DHS) that is responsible for planning for and responding to a public health emergency.

(12) "Pacific Northwest Emergency Management Arrangement" (PNEMA) means the compact, ratified in Chapter 25 Oregon Laws 2008, between the states of Alaska, Idaho, Oregon and Washington, and the Province of British Columbia, and Yukon, to provide mutual assistance in an emergency or public health emergency.

(13) "Public Health Emergency" has the meaning given that term in ORS 433.442.

(14) "Strategic National Stockpile" (SNS) means the US Government stockpile of antiviral drugs and other drugs and medical supplies that can be made available to a state in an emergency.

(15) "Temporary Pharmacy" means a facility established under these rules to temporarily provide pharmacy services within or adjacent to an area subject to a State of Emergency.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: 2008 OL Ch. 25 & ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0040
Delegation of Authority

When these rules are in effect, any authority vested in the Board may be exercised by the Executive Director (ED), any person acting as Executive Director in the ED's absence or incapacity, or any person the ED designates to make such decisions on the ED's behalf.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.165
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0050
Emergency Licensure

(1) Article V of ORS 401.043 (EMAC) and Article V of Annex B of PNEMA provide that whenever a person holds a license, certificate or other permit issued by a signatory to the compact evidencing the meeting of qualifications for professional, mechanical or other skills, and when such assistance is requested by the receiving signatory, the person is deemed to be licensed, certified or permitted by the signatory requesting assistance to render aid involving the skill to meet an emergency or disaster, to the extent allowed by law and subject to limitations and conditions as the requesting signatory prescribes by executive order or otherwise.

(2) When an emergency has been declared, a drug outlet may employ a pharmacist, intern or pharmacy technician who does not hold a license issued by the Board, provided that the individual provides evidence that they hold a comparable license issued by any other state or signatory to PNEMA or EMAC.

(3) In an emergency, the Board may grant an emergency temporary license to a licensee of the board of pharmacy of any state, province, foreign state or political sub-division that is not a signatory to PNEMA or EMAC as follows:

(a) A pharmacist, intern, pharmacy technician or certified pharmacy technician who holds an active license in another state, province, foreign state or political sub-division that is not suspended or restricted for any reason and who is sponsored by a pharmacy that has an active registration from the Board may be granted an emergency temporary license subject to approval by the Board of an application that contains:

(A) The name, permanent address and phone number of the applicant;

(B) The license number and state, province or political sub-division of permanent licensure;

(C) The name and license number of the sponsoring Oregon pharmacy; and

(D) Any other information requested by the Board.

(b) The emergency temporary license issued under these rules shall be valid for a period determined by the Board, but not exceeding six months. If the emergency still exists after six months, the Board may renew any emergency temporary license for an additional six months.

(c) The Board shall notify the sponsoring pharmacy of the approval of each emergency temporary license.

(d) A licensee granted an emergency temporary license under this rule may only practice in the sponsoring pharmacy or a pharmacy under common ownership with the sponsoring pharmacy, except that the licensee may transfer to another pharmacy that is not under common ownership with the sponsoring pharmacy, provided that the licensee notifies the Board within three days.

(4) Inactive License Reactivation: In an emergency, the Board may allow a pharmacist whose license has been inactive for no more than two years to reactivate their license without completing any required continuing education or MPJE. The license will revert to an inactive status at the end of six months unless all required continuing education has been completed.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: 2008 OL Ch. 25, ORS 689.151 & 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0060
SNS and State Stockpile Emergency Drugs

(1) General: When drugs from the Strategic National Stockpile (SNS) are delivered to the state, the drugs may be delivered to a state Receipt, Staging and Storage center (RSS) for further distribution to Points of Dispensing (PODs) selected by OSPHD. State drugs (state stockpile) may also be delivered to the RSS.

(2) Storage of drugs from SNS or state stockpile:

(a) The RSS, PODs and local health departments (LHD) are authorized to store any drugs from the SNS or state stockpile prior to and during an emergency without any registration from the Board.

(b) All such drugs must be stored in accordance with manufacturers' guidelines.

(c) This authority to possess drugs shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused drugs have been completed.

(3) Repackaging: If it is necessary to repackage drugs into unit-of-use regimen packages, this will be done at RSS under Centers for Disease Control (CDC) protocols as follows:

(a) Repackaging equipment will be provided by SNS or OSPHD;

(b) Staff from the CDC Technical Advisory Response Unit (TARU) will train the repackaging team members on the use of the equipment and will provide team leadership.

(c) OSPHD will provide repackaging procedures and team members.

(d) For SNS drugs, unit-of-use regimens shall be labeled in accordance with SNS protocols as follows:

(A) Official health agency name, city and state;

(B) Prescriber's name — when using State protocols prescriber's name will be "State Protocol";

(C) Date repackaged;

(D) Quantity of drugs in the regimen;

(E) Prescription number, name, strength, expiration date and lot number of the drug;

(F) Number for 24-hour telephone line;

(G) Patients name left blank — to be filled in at time of dispensing.

(4) Distribution: The RSS, POD or LHD may distribute or dispense SNS or state stockpile drugs in accordance with the distribution and dispensing procedures provided by OSPHD.

(5) Administration and dispensing: A health-care provider designated by OSPHD or a LHD to supervise the administration and dispensing of SNS or state stockpile drugs shall follow protocols approved by OSPHD, a local health officer or CDC.

(6) An Intake Form that shall serve as a valid prescription is to be filled out for each person receiving a drug at a POD. The intake form is to be retained as specified in OAR 855-007-0110.

(7) Returns: At the conclusion of the emergency, all such drugs are to be returned to the RSS or other designated location under instructions issued by OSPHD.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0080
Emergency Immunization and Drug Distribution

When these rules are in effect, the following principles and procedures shall apply to the distribution, dispensing and administration of vaccines or drugs:

(1) The distribution of vaccines and drugs is to be in accordance with instructions provided by OSPHD.

(2) LHDs are authorized to distribute SNS or state stockpile drugs to designated Treatment Centers (TC) or health-care providers designated by the State Public Health Director or a local health administrator.

(3) A TC may include but is not limited to:

(a) A LHD;

(b) A clinician;

(c) A community health clinic;

(d) An independent or chain pharmacy;

(e) A hospital or other health-care facility;

(f) A temporary pharmacy;

(g) A mobile pharmacy; or

(h) A tribal health-care facility.

(4) A TC may possess, distribute, dispense and administer vaccines and drugs if these rules are in effect.

(5) A health-care provider, designated by the local health administrator, at a TC shall be responsible for administration, distribution and tracking of vaccines and drugs in accordance with procedures established by OSPHD.

(6) A health-care provider may, if permitted under that provider's scope of practice and these rules, distribute, dispense and administer vaccines and drugs.

(7) An Individual Data Collection Form (IDCF) shall be filled out for each person receiving a vaccine or drug at a TC or from a health-care provider, and this IDCF shall be treated as a valid prescription and retained as follows:

(a) An IDCF initiated at a pharmacy or other licensed health-care facility shall be filed and retained for three years;

(b) An IDCF initiated at a facility that is not a licensed health-care facility or at a temporary or mobile pharmacy shall be sent to OSPHD at the end of the state of emergency except that where the temporary or mobile facility has been established under the authority of OAR 855-007-0100 all records shall be filed and retained in accordance with 855-007-0110.

(8) Community Partner: A Community Partner means any entity that is authorized by OSPHD or OBOP to:

(a) Purchase and store vaccines or drugs prior to a pandemic event;

(b) Store vaccines or drugs in a Board registered facility or at a tribal site;

(c) Take possession of the vaccines or drugs and distribute to critical infrastructure and key resources when so directed by OSPHD in accordance with OSPHD protocols and procedures.

(d) A Community Partner shall:

(A) Distribute all drugs within 72 hours of removal from the storage site;

(B) Store all drugs in accordance with manufacture's guidelines;

(C) Record all distributions on a Distribution Log that shall include:

(i) The name and age of the person receiving the drugs;

(ii) The name, strength and quantity of the drugs;

(iii) The date and the time of the distribution.

(e) The Distribution Log shall be treated as a valid prescription and stored or otherwise disposed of as specified in 855-007-0110;

(9) This authority for LHDs, TCs, health-care providers and Community Partners to possess drugs shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused drugs have been completed.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0090
Emergency Pharmacy Rules

(1) Refills: A pharmacist in the area covered by a declared emergency or in an area engaged in disaster assistance may dispense a refill of a prescription drug without a valid prescription provided that:

(a) In the pharmacist's professional judgment, the drug is essential to the maintenance of the patient's health or the continuation of therapy; and

(b) The pharmacist provides no more than a 30-day supply; and

(c) The pharmacist records all relevant information and indicates that it is an Emergency Prescription; and

(d) The pharmacist informs the patient or the patient's agent that the drug is being provided without a prescriber's authorization and that a prescriber authorization is required for any additional refill.

(e) If the refill is for a controlled substance, permission has been granted by the DEA for this type of refill, either by waiver of appropriate controlled substance regulations or by notification to the Board.

(2) New and modified drug therapy: A pharmacist in the area covered by a declared emergency or in an area engaged in disaster assistance may, after consultation with any authorized prescriber, initiate or modify any drug therapy, and dispense an amount of the drug to meet the patient's health needs until that patient can be seen by a health-care practitioner, provided that:

(a) The pharmacist acts in accordance with currently accepted standards of care; and

(b) In the pharmacist's professional judgment, the drug is essential to the maintenance of the patient's health or to the continuation of therapy; and

(c) The pharmacist records all relevant information to a form and indicates that a drug therapy has been initiated or modified and that this is an Emergency Prescription; and

(d) The pharmacist informs the patient or the patient's agent at the time of dispensing that the drug is being provided in the absence of a valid patient — prescriber relationship but that a prescriber was consulted regarding the appropriateness of the drug therapy; and

(e) The pharmacist informs the patient or the patient's agent that a prescriber authorization is required for any refill.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0100
Temporary Pharmacies

(1) When these rules are in effect, the Board may issue a Temporary Pharmacy Registration to any facility or mobile facility.

(2) A facility, including a mobile pharmacy, holding a Temporary Pharmacy Registration may store and dispense drugs in accordance with the requirements of OAR 855-041 and these rules. The supervising pharmacist of a mobile pharmacy shall notify the Board of the pharmacy location within three working days of commencing business, and within three working days of any change in location.

(3) A Temporary Pharmacy Registration automatically expires when the state of emergency ends unless specifically extended by the Board.

(4) Within 30 days of the end of the declared emergency, the holder of a Temporary Pharmacy Registration shall notify the Board as to the disposition of its drug inventory and records.

(5) A temporary or mobile pharmacy that is established for the sole purpose of expediting distribution of emergency immunizations, antibiotics or antiviral drugs under OAR 855-007-0080, is located adjacent to an existing pharmacy registered with the Board and is under the supervision of the PIC of the existing pharmacy, does not need to be registered as a temporary pharmacy.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0110
Emergency Recordkeeping

All records initiated during a state of emergency shall be disposed of as follows:

(1) POD intake forms and Individual Data Collection Forms or electronic records shall be transferred to OSPHD at the end of the emergency;

(2) Community Partner's Logs:

(a) Vaccines: Logs shall be transferred to OSPHD within 14 days of administration to be entered into the statewide immunization information system. If the Community Partner is a registered health-care

facility or under the control of a licensed health-care provider, a copy of the log shall be made before submission and retained for three years.

(b) Antivirals and other drugs: Logs shall be transferred to OSPHD at the end of the emergency unless the Community Partner is a registered health-care facility or under the control of a licensed health-care provider in which case logs shall be stored securely by the Community Partner;

(3) Emergency Prescriptions and Individual Data Collection Forms for drugs dispensed from a pharmacy that is not a Temporary or Mobile Pharmacy shall be stored at the pharmacy.

(4) Emergency Prescriptions and Individual Data Collection Forms for drugs dispensed from a Temporary or Mobile Pharmacy shall be stored at whichever of the following locations is most appropriate:

(a) At the parent pharmacy that provided the majority of the drugs to the Temporary or Mobile Pharmacy; or

(b) At the pharmacy that employs the supervising pharmacist of the Temporary or Mobile Pharmacy; or

(c) At the pharmacy that receives the unused drugs from the Temporary or Mobile Pharmacy at the end of the emergency.

(5) Unless otherwise specified, all records are to be retained for three years and must be made available to the Board upon request.

Stat. Auth.: ORS 401.065, 433.441 & 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

855-007-0120
Damage to a Pharmacy and Drug Integrity

(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, shall be classified as adulterated and must be destroyed unless, in the pharmacist's professional judgment, any items are deemed safe for dispensing. Any incident of this nature must be reported to the Board within three working days.

(2) If a pharmacy loses power that affects temperature or humidity controls such that USP standards for proper storage of drugs have been violated, such drugs shall be classified as adulterated and may not be dispensed.

NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of temperature is 68° to 77°F with allowances for brief deviations between 59° to 86°F.

(3) Controlled substances damaged, lost or stolen shall be documented and reported to the DEA and the Board on DEA Form 41 or DEA Form 106 as appropriate.

(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the Board within three working days.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09

DIVISION 10

BOARD ADMINISTRATION AND POLICIES

855-010-0001
Definitions

(1) "Accredited": In these rules, accredited shall mean a school or college that is currently accredited by the Accreditation Council for Pharmacy Education (ACPE) or that is in a pre-candidate or candidate status with ACPE.

(2) "Board" means Oregon State Board of Pharmacy.

Stat. Auth.: ORS 475.005, 689.205
Stats. Implemented: ORS 689.115
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2007, f. & cert. ef. 6-29-07

855-010-0005
Meetings

(1) The Board meetings shall be held not less than once every three months as designated by the Board.

(2) The President of the Board shall have power to call special meetings, subject to ORS 689.185, when it may be deemed necessary or upon request of a majority of members.

(3) The Board shall hold an annual meeting each year for the election of officers, the reorganization of the Board and the transaction of other business, which may include but is not limited to:

(a) Approval of ACPE programs;

(b) Approval of preceptor sites;

(c) Approval of accredited schools and colleges of pharmacy;

(d) Review and adopt by reference the Federal list of controlled substances.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135, 689.151, 689.185, 689.255
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89; BP 1-2007, f. & cert. ef. 6-29-07

855-010-0015
Individual Commitments

(1) Board members shall be governed by Board action and shall make no individual commitments or promises on matters of Board policies.

(2) No declaration shall be made nor vote taken on any question, except at Board meetings. However, after due notification to each Board member, emergency votes may be taken by telephone conference or mail ballot of a majority of Board members, such vote to be confirmed at the next Board meeting.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-010-0021
Adoption by Reference

All outside standards, statutes, rules and publications referred to in any rules adopted by the Board are by those references made a part of those rules as though fully set forth. Copies are available in the office of the Board of Pharmacy.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80

855-010-0035
Board Compliance Program

The Board's Compliance Director and Pharmacy Inspectors shall be pharmacists licensed in the State of Oregon.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 6-1989, f. & cert. ef. 4-27-89

855-010-0045
State and Nationwide Criminal Background Checks

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; and individuals subject to investigation by the Board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the Board.

(2) "Subject individual" means a person from whom the Board may require fingerprints for the purpose of enabling the Board to request a state or nationwide criminal records check. In this rule, subject individual means: applicants for licensure or renewal of a license; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; and individuals subject to an investigation by the Board.

(3) This rule is to be applied when evaluating the criminal history of a subject individual and conducting fitness determinations based upon such history. The fact that a subject individual does not have an adverse criminal history does not guarantee the granting or renewal of a license, or registration.

(4) The Board may request that the Department of State Police conduct a state criminal history check and a national criminal history check, using fingerprint identification of subject individuals. The Board may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the Department of State Police in accordance with rules adopted, and procedures established, by the Department of State Police. Criminal history information obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181, OAR 257-010 to 257-015 and applicable Oregon State Police procedures.

(5) Additional Information Required. In order to conduct a state and national criminal history check and fitness determination, the Board may require additional information from the subject individual as necessary. Additional information may include but is not limited to, proof of identity; residential history; names used while living at each residence; or additional criminal, judicial, or other background information.

(6) In making the fitness determination, the Board may consider:

(a) The nature of any record that may include but is not limited to any record of arrest or conviction for:

(A) Any drug or alcohol offence;

(B) Any felony;

(C) Any offence involving fraud, theft, identity theft or other instance of dishonesty;

(D) Any offence involving violation of federal importation or customs laws or rules;

(E) Any offence requiring registration as a sex offender.

(b) The facts that support the conviction or indictment or that indicate the making of the false statement;

(c) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(d) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer.

(e) Any false statement made by the individual regarding the criminal history of the individual;

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(7) If a subject individual is determined to be unfit, then the individual may not be granted a license or registration or a renewal of a license or registration. The Board may make a fitness determination conditional upon applicant's acceptance of probation, conditions, limitations, or other restrictions upon licensure or registration.

(8) All background checks shall be requested to include available state and national data, unless obtaining one or the other is an acceptable alternative.

(9) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check shall be destroyed by either the Federal Bureau of Investigation or the Department of State Police as specified in ORS 181.534.

(10) The Board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(11) If an applicant, licensee or certificate holder is determined not to be fit for a license or registration, they are entitled to a contested case hearing pursuant to ORS 183.413 to 470 and in accordance with OAR 855-001-0005 to 0017.

(12) A challenge to the accuracy or completeness of information provided by the Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.

(13) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon State Police, the Federal Bureau of Investigation or other agency reporting information to the Board, the Board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

(14) If the subject individual discontinues the application or fails to cooperate with the criminal history check process then the application is considered incomplete.

(15) Subject individuals will be required to pay the actual costs charged by the Department of State Police for the state and national criminal background check.

Stat. Auth.: ORS 181.534, 689.205
Stats. Implemented: ORS 689.207
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

DIVISION 11

HEALTH PROFESSIONAL'S SERVICE PROGRAM

855-011-0005
Definitions

When used in this division of rules:

(1) "Health Professional's Service Program (the Program)" means the impaired health professional program established by the Oregon Health Authority pursuant to authority granted by ORS 676.190.

(2) "Impaired" means that the licensee is unable to practice with professional skill and safety by reason of habitual or excessive use or abuse of drugs, alcohol or other substances or by reason of a mental health disorder.

(3) "Mental-health disorder" means a clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is associated with present distress or disability or with a significantly increased risk of suffering death, pain, disability, or an important loss of freedom that is identified in the DSM-IV-TR, (published by the American Psychiatric Association). "Mental-health disorder" includes gambling disorders.

(4) "Non-treatment compliance monitoring," means the non-medical, non-therapeutic services employed by the vendor to track and report the licensee's compliance with the monitoring agreement.

(5) "Substance Abuse Disorder" means a disorder related to the taking of a drug of abuse including alcohol, to the side effects of a medication, and to a toxin exposure. The disorders include: substance abuse disorders such as substance dependence and substance abuse, and substance-induced disorders, including substance intoxication, withdrawal, delirium, and dementia, as well as substance induced psychotic disorder, mood disorder, etc, as defined in DSM-IV-TR, (published by the American Psychiatric Association) criteria.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10

855-011-0020
Participation in Health Professional's Service Program

(1) Effective July 1, 2010, the Oregon Board of Pharmacy (Board) will participate in the Program.

(2) The Board may only refer licensees of the Board to the Program if they meet the referral criteria established by the Board.

(3) The Board may refer a licensee to the Program in lieu of or in addition to public discipline.

(4) A licensee who has not been referred to the Program by the Board may participate in the Program as permitted by ORS 676.190(5). Licensees may not refer themselves to the Program unless they certify that, to the best of their knowledge, they are not currently under investigation by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10

855-011-0030
Procedure to refer Board licensees to the Program

(1) When the Board has information that a licensee may be impaired by alcohol or a substance abuse disorder or dependency, or a mental-health disorder, the Board may consider referring the licensee to the Program.

(2) Before the Board refers a licensee to the Program, the Board shall:

(a) Obtain a copy of a written report that diagnoses the licensee with alcohol or a substance abuse disorder or dependency, or a mental-health disorder and provides treatment options;

(b) Investigate to determine whether the licensee's professional practice while impaired has presented or presents a danger to the public;

(c) Obtain the licensee's written agreement to report any arrest for or conviction of a misdemeanor or felony to the Board within three business days after the licensee is arrested or convicted;

(d) Obtain the licensee's written agreement to pay the costs of participation in the Program, including the cost of laboratory or toxicology tests, treatment, consultation group meetings and evaluations; and

(e) Obtain the licensee's written consent allowing disclosure and exchange of information between the Program, the Board, the monitoring entity, the licensee's employers, and evaluators and treatment entities.

(3) The report referred to in subsection (2)(a) of this rule must be prepared by an independent evaluator approved by the Board under OAR 855-011-0040 to evaluate alcohol or a substance abuse disorder or dependency, and mental-health disorders.

(4) The Board may only refer to the Program a licensee who has been diagnosed with alcohol or a substance abuse disorder or dependency, or a mental health disorder.

(5) The Board will consider all relevant factors before determining whether to refer a licensee to the Program. Relevant factors shall include but are not limited to:

(a) Licensee's disciplinary history;

(b) The severity and duration of the licensee's impairment;

(c) The extent to which licensee's practice can be limited or managed to eliminate danger to the public;

(d) The likelihood that licensee's impairment can be managed with treatment; and

(e) The likelihood that the licensee will follow the conditions of the program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10

855-011-0040
Approval by the Board of an Independent Evaluator

(1) The Board may approve a person to act as an evaluator provided that the person:

(a) Is licensed as required by the jurisdiction in which they work;

(b) Possesses a masters degree or a doctorate in a mental health discipline;

(c) Can document training and experience in one of the following:

(A) US Department of Transportation, Substance Abuse Professional Qualification training;

(B) Certification by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission as a Certified Alcohol and Drug Abuse Counselor (CADC) level II or III; or

(C) Board certification in Addiction Medicine by either the American Society of Addiction Medicine or American Board of Psychiatry and Neurology.

(d) Is able to provide a multi-disciplinary assessment and written report describing a licensee's diagnosis, degree of impairment and treatment options; and

(e) Certifies that, if required, they are willing to defend their evaluation in a court of law.

(2) The Board may not approve an evaluator in a case if, in the Board's judgment, the evaluator's judgment is likely to be influenced by a personal or professional relationship with a licensee.

(3) The Board shall maintain a list of approved independent evaluators on the Board's website or the Board may approve a list of evaluators that meet the above criteria that is approved and published by the Program contractor.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10

855-011-0050
Additional requirements for licensees referred to the Program

(1) In addition to the requirements established by ORS 676.185 to 676.200, a licensee who participates in the Program must:

(a) Participate in the Program for as long as specified in the disciplinary order but not less than two years, except that a licensee who has been enrolled in a prior Board approved program for at least two years may count up to one year of that program towards this requirement;

(b) Meet all conditions of probation specified in the disciplinary order; and

(c) Pay all costs of attendance at non-treatment compliance monitoring group meetings.

(2) A licensee may petition the Board for early removal from the Program if:

(a) They are in good standing with the Program;

(b) They have been in the Program for at least two years; and

(c) They have complied with all conditions of their Board disciplinary order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10

DIVISION 19

LICENSING OF PHARMACISTS

855-019-0100
Application

(1) These rules apply to any pharmacist who is licensed to practice pharmacy in Oregon including any pharmacist located in another state who is consulting, or providing any other pharmacist service, for a patient, pharmacy or healthcare facility in Oregon.

(2) Where so indicated, these rules also apply to an intern who is licensed in Oregon.

(3) Any pharmacist who engages in the practice of pharmacy in Oregon must be licensed by the Board in accordance with the following rules.

(4) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).

(5) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.255
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

855-019-0110
Definitions

In this Division of Rules:

(1) "Collaborative Drug Therapy Management (CDTM)" has the same meaning as defined in OAR 855-006-0005.

(2) "Counseling" means an oral or other appropriate communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient or patient's agent, and, where appropriate, the patient's pharmacy records, assesses that information and provides the patient or patient's agent with professional advice regarding the safe and effective use of the drug or device for the purpose of assuring therapeutic appropriateness.

(3) "Drug Regimen Review (DRR)" means the process conducted by a pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.

(4) "Drug Utilization Review (DUR)" has the same meaning as defined in OAR 855-006-0005.

(5) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

Licensing

855-019-0120
Licensure

Before licensure as a pharmacist, an applicant must meet the following requirements:

(1) Provide evidence from a school or college of pharmacy approved by the Board that they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-031-0005, and that a degree will be conferred;

(2) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. This score shall remain valid for only one year unless the Board grants an extension. A candidate who does not attain this score may retake the exam after a minimum of 91 days;

(3) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MJPE until they have graduated from a school or college of pharmacy approved by the Board. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MJPE score shall be valid for 6 months unless extended by the Board;

(4) Submit a completed application form that may be obtained from the Board office, and pay the fee specified in Division 110 of this chapter of rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; 1PB 3-1985, f. & ef. 12-2-85; PB 3-1991, f. & cert. ef. 9-19-91; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0005, BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-019-0125
Coaching from Board and Staff

No member or employee of the Board shall discuss the contents of an examination, its preparation or use with any candidate or other person. No member or employee of the Board shall coach a candidate or any other person on materials that may be used in the examination nor shall they accept any fees for any act of assistance that would bear on the examination.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0010, BP 2-2008, f. & cert. ef. 2-20-08

855-019-0130
Licensure by Reciprocity

(1) An applicant for licensure as a pharmacist by reciprocity must meet the requirements of ORS 689.265 and the following requirements:

(a) Be a graduate of a school or college of pharmacy approved by the Board;

(b) Have passed the NAPLEX or equivalent examination with a score of not less than 75;

(c) Have passed the MPJE with a score of not less than 75;

(d) Be licensed and in good standing in the state from which the applicant bases the reciprocity application;

(e) Have either:

(A) Been engaged in the practice of pharmacy for period of at least one year including a minimum of 1440 hours of work experience as a licensed pharmacist. Evidence supporting this work experience shall be provided at time of application; or

(B) Met the internship requirements of this state within the one-year period immediately before the date of this application. Evidence from the school or college of pharmacy supporting this internship shall be provided at time of application.

(2) Licensure as a pharmacist in another state precludes licensure to practice as an intern in the State of Oregon, except for applicants for licensure by examination or by reciprocity who must acquire internship hours to become eligible for licensure, and then only until the required hours have been acquired.

(3) An applicant who has obtained their professional degree outside the United States is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-019-0150.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151 & 689.265
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1981, f. & ef. 8-20-81; 1PB 1-1984, f. & ef. 2-16-84; PB 1-1989, f. & cert. ef. 1-3-89; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-019-0015 & 855-019-0030, BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-019-0140
NAPLEX Score Transfer

(1) An applicant for score transfer must be a graduate of a school or college of pharmacy approved by the Board and must have passed the NAPLEX or equivalent examination with a score of at least 75.

(2) Prior to taking the NAPLEX examination for their initial state of licensure, an applicant must have requested the National Association of Boards of Pharmacy to score transfer their NAPLEX score to Oregon.

(3) An applicant must provide the following documentation:

(a) Oregon Score Transfer Application;

(b) A passport regulation photograph;

(c) A copy of a birth certificate, US passport or naturalization documents, or a foreign passport endorsed with a US visa permitting full time employment;

(d) Evidence of successful completion of all graduation requirements from a school or college of pharmacy approved by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.265
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0025, BP 2-2008, f. & cert. ef. 2-20-08

855-019-0150
Foreign Pharmacy Graduates

(1) Foreign Pharmacy Graduates applying for licensure in Oregon must meet the following requirements:

(a) Provide a copy of a valid visa permitting full time employment;

(b) Provide the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and

(c) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT) with a minimum score of 26 in Speaking, 21 in Reading, 18 in Listening and 24 in Writing, however scores will be accepted until June 30, 2010 from candidates who have already passed or are scheduled to take the TOEFL and the Test of Spoken English (TSE).

(d) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;

(e) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.

(2) An applicant must complete 1440 hours in pharmacy practice as an intern that must be certified to the Board by the preceptors.

(3) An applicant may not count internship hours or practice as a pharmacist completed outside the United States toward Oregon's internship requirement.

(4) An applicant may not count internship hours or practice as a pharmacist that is completed before passing the Foreign Pharmacy Graduate Equivalency Examination, and either the TOEFL with TSE, or TOEFL (IBT) exams toward Oregon's internship requirement.

(5) The Board may waive any requirement of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151 & 689.255
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-019-0160
Nuclear Pharmacists

In order to qualify under these rules as a nuclear pharmacist, a pharmacist shall:

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and

(2) Be a pharmacist licensed to practice in Oregon; and

(3) Submit to the Board of Pharmacy either:

(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmaceutical Specialties; or

(b) Evidence that they meet both the following:

(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and

(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the Board.

(4) Receive a letter of notification from the Board that the evidence submitted by the pharmacist meets the above requirements and has been accepted by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: PB 7-1987, f. & ef. 7-8-87; PB 1-1994, f. & cert. ef. 2-2-94: Renumbered from 855-042-0020, BP 2-2008, f. & cert. ef. 2-20-08

855-019-0170
Reinstatement of License

(1) A pharmacist who fails to renew their license by the deadline may reinstate their license as follows:

(a) By payment of the annual license fees and delinquency fees for all years during which the license was lapsed and for the current year; and

(b) By providing certification of completion of the continuing education requirement for all years in which the license was lapsed; and

(c) If their license has been lapsed for more than one year, pass the MPJE with a score of not less than 75.

(2) A pharmacist in good standing who retired from the practice of pharmacy after having been licensed for not less than 20 years need only pay the annual license fees for the year in which they seek a license, however they must provide certification of completion of continuing education for all years since their retirement and pass the MPJE with a score of not less than 75.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.275
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1981, f. & ef. 8-20-81; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0040, BP 2-2008, f. & cert. ef. 2-20-08

Pharmacist Practice

855-019-0200
General Responsibilities of a Pharmacist

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.

(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.

(2) A pharmacist shall perform the duties of a pharmacist that include, but are not limited to, DUR, counseling, and final verification of the work performed by those under their supervision.

(3) A pharmacist may not delegate any task that requires the professional judgment of a pharmacist. Such tasks include but are not limited to:

(a) Counseling to a patient or patient's agent, or other healthcare provider;

(b) Verification;

(c) Performing DUR;

(d) Providing a CDTM, DRR, or MTM service;

(e) Ordering, interpreting and monitoring of a laboratory test; and

(f) Oral receipt or transfer of a prescription; except that

(g) An intern under the supervision of a pharmacist may perform all the duties of a technician and the following:

(A) Counseling;

(B) Performing DUR;

(C) Oral receipt or transfer of a prescription,

(D) Immunizations if appropriately trained, and supervised by an immunization qualified pharmacist;

(E) Other activities approved in writing by the Board.

(4) A pharmacist who is supervising an intern is responsible for the actions of that intern, however, this does not absolve the intern from responsibility for their own actions.

(5) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.

(6) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.

(7) A pharmacist while on duty is responsible for the security of the pharmacy area including:

(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;

(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;

(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.025, 689.151, 689.155
Hist.: PB 15-1989, f. & cert. ef. 12-26-89; PB 2-1997(Temp), f. 10-2-97, cert. ef. 10-4-97; BP 2-1998, f. & cert. ef. 3-23-98; Renumbered from 855-041-0210, BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

855-019-0205
Duty to Report

(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.

(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(3) A pharmacist must report to the Board within 10 days if they:

(a) Are convicted of a misdemeanor or a felony; or

(b) If they are arrested for a felony.

(4) A pharmacist who has reasonable cause to believe that another licensee (of the Board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting pharmacist shall report the conduct without undue delay, but in no event later than 10 working days after the pharmacist learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.

(5) A pharmacist who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.

(6) A pharmacist who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the Board within 10 days.

(7) A pharmacist must notify the Board in writing, within 15 days, of any change in employment location or residence address.

Stat. Auth.: ORS 689.205
Stats. Implemented: 689.151, 689.155, OL 2009, Ch. 536
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-019-0210
Duties of the Pharmacist Receiving a Prescription

(1) A pharmacist must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed or prepared for administration in accordance with the prescribing practitioner's authorization.

(2) A pharmacist receiving a prescription is responsible for:

(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the pre-

scription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and not result solely from a questionnaire or an internet-based relationship; and

(b) Ensuring that the prescription contains all the information specified in Division 41 of this chapter of rules including the legible name and contact phone number of the prescribing practitioner for verification purposes.

(3) A pharmacist may refuse to dispense a prescription to any person who lacks proper identification.

(4) Oral Prescription: Upon receipt of an oral prescription, the pharmacist shall promptly reduce the oral prescription to writing or create a permanent electronic record by recording:

(a) The date when the oral prescription was received;

(b) The name of the patient for whom, or the owner of the animal for which, the drug is to be dispensed;

(c) The full name and, in the case of controlled substances, the address and the DEA registration number, of the practitioner, or other number as authorized under rules adopted by reference under Division 80 of this chapter of rules;

(d) If the oral prescription is for an animal, the species of the animal for which the drug is prescribed;

(e) The name, strength, dosage form of the substance, quantity prescribed;

(f) The direction for use;

(g) The total number of refills authorized by the prescribing practitioner;

(h) The written signature or initials or electronic identifier of the receiving pharmacist or intern and the identity of the person transmitting the prescription;

(i) The written or electronic record of the oral prescription must be retained on file as required by Division 41 of this chapter of rules, and in the case of controlled substances, under rules adopted by reference in Division 80 of this chapter of rules.

(5) Facsimile Prescription: Upon receipt of a facsimile prescription, the pharmacist must be confident that the prescription was sent by an authorized practitioner or practitioner's agent, and they must verify that:

(a) The facsimile contains all the information specified in division 41 and division 80 of this chapter of rules; and

(b) The facsimile prescription is not for a Schedule II controlled substance unless so permitted under federal regulations or division 80 of this chapter of rules; and

(c) If the facsimile prescription is for a controlled substance, the prescription contains an original, manually-signed signature of the prescriber. In this rule, manually-signed specifically excludes a signature stamp or any form of digital signature unless permitted under federal regulations.

(6) Electronic Prescription: Before filling a prescription that has been received electronically, the pharmacist must be confident that:

(a) The prescription was originated by an authorized practitioner or practitioner's agent;

(b) The prescription contains all the information specified in Division 41 of this chapter of rules.

(c) The prescription is not for a controlled substance unless permitted by federal regulations.

(7) The pharmacist must ensure that a written prescription that is hand-carried or mailed into the pharmacy contains an original manually-signed signature of the prescribing practitioner or practitioner's agent.

(8) Computer Transfer of Prescription Information between Pharmacies: A pharmacist that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:

(a) The accurate transfer of prescription information between pharmacies;

(b) The creation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the pharmacist will use in verifying the prescription;

(c) The prescription is invalidated at the sending pharmacy; and

(d) Compliance with all relevant state and federal laws and rules regarding the transfer of controlled substance prescriptions.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; Renumbered from 855-041-0085, BP 2-2008, f. & cert. ef. 2-20-08

Pharmacist Care and Practice

855-019-0220
Drug Utilization Review (DUR)

(1) A pharmacist shall maintain a record for each patient that contains easily retrievable information necessary for the pharmacist to perform a DUR and to identify previously dispensed drugs at the time a prescription or drug order is presented for dispensing or preparing for administration. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(a) Full name of the patient for whom the drug is prescribed;

(b) Address and telephone number of the patient;

(c) Patient's gender, age or date of birth;

(d) Chronic medical conditions and disease states of the patient;

(e) A list of all drugs or devices the patient is currently obtaining at that pharmacy showing the name of the drug or device, strength of the drug, the quantity and date received, and the name of the prescribing practitioner;

(f) Known allergies, adverse drug reactions, and drug idiosyncrasies;

(g) Pharmacist comments relevant to the individual's drug therapy, including any other information specific to that patient or drug; and

(h) Additional information, which may relate to DUR, or for the monitoring of the patient as appropriate.

(2) Patient records shall be maintained for at least three years.

(3) The pharmacist or intern shall perform a DUR prior to dispensing or preparing for administration any prescription or refill.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-019-0230
Counseling

(1) The pharmacist or intern shall orally counsel the patient or patient's agent on the use of a drug or device as appropriate:

(a) The pharmacist or intern shall counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;

(b) Only the pharmacist or intern may accept a patient's or patient's agent's request not to be counseled. If, in their professional judgment, the pharmacist or intern believes that the patient's safety may be affected, the pharmacist or intern may choose not to release the prescription until counseling has been completed;

(c) Effective July 1, 2008, the pharmacist or intern that provides counseling or accepts the request not to be counseled shall document the interaction;

(d) A pharmacist shall not allow non-pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;

(e) For a prescription 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;

(f) For each patient, the pharmacist or intern shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(2) Counseling on a refill prescription shall be such as a reasonable and prudent pharmacist would provide including but not limited to changes in strength or directions.

(3) A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A pharmacist or intern shall initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the pharmacist must ensure that the patient receives appropriate counseling.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90; PB 5-1992, f. & cert. ef. 10-23-92; PB 1-1994, f. & cert. ef. 2-2-94; BP 4-1998, f. & cert. ef. 8-14-98; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-041-0100, BP 2-2008, f. & cert. ef. 2-20-08

855-019-0240
Consulting Pharmacist Practice

(1) Subject to the provisions of OAR 855-019-0100(4), a consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist.

(2) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.

(3) A consulting pharmacist must maintain appropriate records of their consulting activities for three years, and make them available to the Board for inspection.

(4) A consulting pharmacist is responsible for the safe custody and security of all their records and must comply with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

(5) A consulting pharmacist for a facility that is required by the Board to have a consultant pharmacist but which does not have additional consulting requirements under the terms of its licensure with any other state agency, shall provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

(b) Provide guidance on the proper documentation of drug administration or dispensing;

(c) Provide educational materials or programs as requested.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

855-019-0250
Medication Therapy Management

(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provide by a pharmacist or can be in conjunction with the provision of a medication product with the objectives of:

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between practitioner and pharmacist; and

(e) Improving outcomes.

(2) A pharmacist that provides MTM services shall ensure that they are provided according to the individual needs of the patient and may include but are not limited to the following:

(a) Performing or otherwise obtaining the patient's health status assessment;

(b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;

(c) Monitoring the safety and effectiveness of the medication therapy;

(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;

(e) Performing a medication review to identify, prevent or resolve medication related problems;

(f) Monitoring the patient for adverse drug events;

(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication;

(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records shall:

(A) Provide accountability and an audit trail; and

(B) Be preserved for at least three years and be made available to the Board upon request except that when records are maintained by an outside contractor, the contract must specify that the records be retained by the contractor and made available to the Board for at least three years.

(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen;

(j) Integrating the medication therapy management services within the overall health management plan for the patient; and

(k) Providing for the safe custody and security of all records and compliance with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

855-019-0260
Collaborative Drug Therapy Management

(1) As used in this rule "Collaborative Drug Therapy Management" means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one practitioner and one pharmacist; or

(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.

(2) A pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes:

(a) The identification, either by name or by description, of each of the participating pharmacists;

(b) The identification, by name or description, of each of the participating practitioners or group of practitioners;

(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;

(d) The types of decisions that the pharmacist is allowed to make, which may include:

(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;

(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;

(C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;

(D) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.

(e) Training requirement for pharmacist participation and ongoing assessment of competency, if necessary;

(f) Quality assurance and periodic review by a panel of the participating pharmacists and practitioners;

(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and

(h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years;

(3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: Hist.: BP 4-1998, f. & cert. ef. 8-14-98; BP 1-1999(Temp), f. & cert. ef. 1-29-99 thru 7-28-99; Administrative correction 8-9-99; BP 1-2000, f. & cert. ef. 2-16-00; Renumbered from 855-041-0400, BP 2-2008, f. & cert. ef. 2-20-08

Administration of Vaccines by Pharmacists

855-019-0270
Qualifications

(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of

this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.

(2) A pharmacist may administer vaccines to persons who are at least 11 years of age as provided by these rules. For the purposes of this rule, a person is at least 11 years of age on the day of the person's eleventh birthday.

(3) A pharmacist may administer vaccines under Section (1) or Section (2) of this rule only if:

(a) The pharmacist has completed a course of training approved by the Board;

(b) The pharmacist holds a current basic Cardiopulmonary Resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or any other equivalent program that contains a hands-on training component and is valid for not more than three years, and documentation of the certification is placed on file in the pharmacy;

(c) The vaccines are administered in accordance with an administration protocol written and approved by the Oregon Health Authority (OHA); and

(d) The pharmacist has a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."

(4) A pharmacist may not delegate the administration of vaccines to another person.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.645

Hist.: BP 7-2000, f. & cert. ef. 6-29-00; BP 3-2006, f. & cert. ef. 6-9-06; BP 1-2007, f. & cert. ef. 6-29-07; Renumbered from 855-041-0500, BP 2-2008, f. & cert. ef. 2-20-08; BP 11-2010, f. 10-22-10, cert. ef. 1-1-11

855-019-0280
Protocols, Policies and Procedures

(1) Prior to administering a vaccine to a person who is at least 11 years of age a pharmacist must follow protocols written and approved by the OHA for administration of vaccines and the treatment of severe adverse events following administration of a vaccine.

(2) The pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.

(3) The pharmacist must give the appropriate Vaccine Information Statement (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine.

(4) The pharmacist must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.

(5) The pharmacist should give the Adolescent Well Visit Referral document, provided by the OHA, to a patient aged 11-18 years of age or their legal representative when it is available.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.645

Hist.: BP 7-2000, f. & cert. ef. 6-29-00; BP 3-2006, f. & cert. ef. 6-9-06: Renumbered from 855-041-0510, BP 2-2008, f. & cert. ef. 2-20-08; BP 11-2010, f. 10-22-10, cert. ef. 1-1-11

855-019-0290
Record Keeping and Reporting

(1) A pharmacist who administers any vaccine must maintain the following information in the pharmacy records regarding each administration for a minimum of three years:

(a) The name, address, gender and date of birth of the patient, and phone number when available;

(b) The date and site of the administration of the vaccine;

(c) The brand name, or NDC number, or other acceptable standardized vaccine code set, dose, manufacturer, lot number, and expiration date of the vaccine;

(d) The name or identifiable initials of the administering pharmacist;

(e) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;

(f) The date of publication of the VIS; and

(g) The date the VIS was provided.

(2) If providing state or federal vaccines, the vaccine eligibility code as specified by the OHA must be reported to the ALERT system.

(3) A pharmacist who administers any vaccine must report, the elements of Section (1), and Section (2) of this rule if applicable, to the OHA ALERT Immunization System within 15 days of administration. This replaces the former requirement to notify the primary health care provider.

(4) A pharmacist who administers any vaccine will keep documentation of current CPR training. This documentation will be kept on site and available for inspection.

(5) A pharmacist who administers any vaccine will follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.645

Hist.: BP 7-2000, f. & cert. ef. 6-29-00; BP 3-2006, f. & cert. ef. 6-9-06: Renumbered from 855-041-0520, BP 2-2008, f. & cert. ef. 2-20-08; BP 11-2010, f. 10-22-10, cert. ef. 1-1-11

Pharmacist-in-Charge

855-019-0300
Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.

(2) In order to be a PIC, a pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a Board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the Board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of the occurrence, on a form provided by the Board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board;

(f) If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.

(g) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the Board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the Board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

(h) The records and forms required by this section must be filed in the pharmacy, made available to the Board for inspection upon request, and must be retained for three years.

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

Discipline

855-019-0310
Grounds for Discipline

The State Board of Pharmacy may suspend, revoke, or restrict the license of a pharmacist or intern or may impose a civil penalty upon the pharmacist or intern upon the following grounds:

(1) Unprofessional conduct as defined in OAR 855-006-0005;

(2) Repeated or gross negligence;

(3) Impairment, which means an inability to practice with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;

(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;

(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;

(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;

(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a license to practice pharmacy or a drug outlet registration;

(8) Permitting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;

(9) Aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;

(10) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto; or

(11) Failure to perform appropriately the duties of a pharmacist while engaging in the practice of pharmacy as defined in ORS 689.005.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.405, OL 2009, Ch. 756
Hist.: PB 1-1989, f. & cert. ef. 1-3-89; BP 1-2002, f. & cert. ef. 1-8-02; BP 6-2005(Temp), f. & cert. ef. 6-28-05 thru 12-13-05; Administrative correction 12-20-05; Renumbered from 855-019-0055, BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10

855-019-0320
Petition for Reinstatement of Pharmacist Licenses

(1) A pharmacist license which has been revoked, suspended or restricted will be reinstated only if the Board finds, upon a presentation made by the petitioner, that there is a reasonable assurance that the public interest will be protected if relicensure occurs.

(2) A presentation must consist of a showing by the petitioner of changed circumstances from those surrounding the revocation, suspension or restriction of license. The presentation must include:

(a) A showing that the petitioner has engaged in treatment, programs, or other endeavors or activities since the suspension, revocation or restriction of license which has caused the rehabilitation of the petitioner to the extent that the public's interest would be protected if relicensure should be granted.

(b) Medical, psychological, sociological or other physical, mental or moral appraisals, evaluations or recommendations relating to the petitioner to aid the Board in its determination whether the petitioner has been rehabilitated to the extent that the public's interest would be protected if relicensure should be granted.

(3) Petitions to the Board for reinstatement of licensure after suspension, revocation or restriction must be in writing and must contain:

(a) A written statement of those changed circumstances which the petitioner believes warrant the Board's finding that there is a reasonable assurance that the public interest will be protected if relicensure occurs. Such statement must include a recitation of the treatment, programs, or other endeavors or activities undertaken by the petitioner, more particularly referred to subsection (2)(a) of this rule.

(b) A summarization of the medical, psychological, sociological or other physical, mental, or moral appraisals or recommendations which the petitioner intends to present to the Board pursuant to subsection (2)(b) of this rule.

(4) If, after opportunity is afforded the petitioner to show otherwise, the Board determines that a petition fails to comply with section (3) of this rule, or has not been made within a reasonable interval from the suspension, revocation, or restriction of license or from a previous petition, the Board will dismiss the petition without further investigation and hearing before the Board.

(5) Petitions which comply with section (3) of this rule will be scheduled for presentation of proof before the Board, and the petitioner will be notified of the time and place.

(6) The completion of any treatment, program or activity which the Board may recommend does not establish a right to reinstatement. The Board must, in each and every case, make a finding based upon the presentation of the petitioner that there is a reasonable assurance that the public interest will be protected if relicensure occurs.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.445
Hist.: 1PB 1-1982, f. & ef. 3-8-82; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0050, BP 2-2008, f. & cert. ef. 2-20-08

DIVISION 21

CONTINUING PHARMACY EDUCATION

855-021-0005
Continuing Pharmacy Education Required for Pharmacist License Renewal

(1) During the period from June 1 through May 31 of each license renewal cycle, each pharmacist must have satisfactorily completed one and one half (1.5) continuing pharmacy education units (CEU's) in an approved continuing pharmacy education program Ten contact hours equals 1 CEU. Fifty minutes equals 1 contact hour.

(2) Section (1) does not apply to pharmacists applying for the first annual renewal of their license if they have not been licensed by the Board for at least one year prior to July 1 of the renewal period.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.285
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04

855-021-0010
Continuing Pharmacy Education

(1) A continuing pharmacy education program means classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self study courses, cassette or audio visual tape/slides or materials, and other self instruction units:

(a) A program shall consist of therapeutics, or pharmacy and drug law or other aspects of health care. At least eleven of the required fifteen hours of continuing education credit must be earned in the areas of therapeutics. At least one hour of continuing education credit must be earned in the area of pharmacy and drug law.

(b) Programs shall provide for examinations or other methods of evaluation to assure satisfactory completion by participants.

(c) The person or persons who are to instruct or who are responsible for the delivery or content of the program shall be qualified in the subject matter by education and experience.

(2) Continuing pharmacy education programs shall be approved by the Board of Pharmacy. Application for approval shall be made on and in accordance with forms established by the Board. The forms shall require information relating to:

(a) Name of provider or sponsor;

(b) Type of program offered;

(c) Description of subject matter;

(d) Number of contact hours offered;

(e) Total number of contact hours in therapeutics or pharmacy and drug law or other aspects of health care;

(f) Method of determining satisfactory completion of program;

(g) Dates and location of program;

(h) Name and qualification of instructors or other persons responsible for the delivery or content of the program.

(3) CE programs are not required to carry approval of American Council on Pharmaceutical Education (ACPE). Programs presented by providers approved by the American Council on Pharmacy Education (ACPE) are generally accepted, however, the Board reserves the right to determine the number of hours allowed or to disapprove such programs.

(4) Providers shall provide attendees with proof of attendance that shows the date and number of contact hours provided. Providers must maintain attendance lists for three years.

(5) Continuing pharmacy education credit accumulated in excess of the required 15 contact hours for annual license renewal cannot be carried forward.

(6) A maximum of 10 hours (1.0 CEU) may be earned in any licensing year by preparing and presenting CE programs. Pharmacists presenting CE programs may earn one hour (0.1 CEU) for preparation time of one hour or more, plus credit for the actual contact hour time of the presentation. A pharmacist must show content of the course, and a description of the intended audience (e.g., pharmacists, physicians, nurses). Public service programs, such as presentations to school children or service clubs, are not eligible for continuing education credit.

(7) Pharmacists taking post graduate studies applicable to graduate or professional degrees may submit the course syllabus and evidence of satisfactory completion of the course for continuing education credit approval by the Board.

(8) The Board may approve up to 14 (fourteen) hours of CE credit for licensees who have successfully completed Disease State Management courses certified by the NIPCO, NISPC, BPST, or other appropriate certified programs sponsored by established credentialing groups.

(9) Board members or staff may attend CE programs for the purpose of evaluating content, format and appropriateness of material for Continuing Pharmacy Education credit. Subsequent programs by CE providers whose current programs are deemed deficient by on-site evaluation may be required to obtain prior approval by the Board. The Board will provide feedback to CE providers regarding evaluated CE presentations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.285
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1984, f. & ef. 3-7-84; 1PB 1-1986, f. & ef. 6-5-86; PB 10-1987, f. & ef. 12-8-87; PB 3-1991, f. & cert. ef. 9-19-91; PB 4-1992, f. & cert. ef. 8-25-92; BP 5-2000(Temp), f. 6-20-00, cert. ef. 6-20-00 thru 10-27-00; Administrative correction 6-21-01; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04

855-021-0016
Continuing Education in Pain Management

(1) A pharmacist licensed under these rules must complete seven hours of continuing education in pain management as detailed in the following sub-sections. This is a one–time requirement:

(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management Commission of the Oregon Department of Human Services; and

(b) A minimum of six hours of continuing education in pain management. This requirement may be fulfilled by any combination of continuing education coursework focusing on pain management including but not limited to the treatment of terminally ill and dying patients, and those with chronic, non-malignant pain.

(2) A licensee must complete the required continuing education within 24 months of their first license renewal after January 2, 2006.

(3) A licensee must retain for three years, documentation showing they have met the requirement of this rule, and must provide this documentation if requested by the Board.

(4) The pain management continuing education required under this rule shall count towards the 1.5 continuing pharmacy education units required under OAR 855-021-0005, in the license cycle in which the pain management continuing education is completed. Any portion of this continuing education may count towards the requirement in OAR 855-021-0010(1)(a) for 11 hours continuing education in therapeutics.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.285, 409.560 & 409.565
Hist.: BP 7-2006(Temp) f. & cert. ef. 8-25-06 thru 1-20-07; BP 11-2006, f. & cert. ef. 12-19-06

855-021-0025
Continuing Pharmacy Education — Reciprocity

Continuing pharmacy education will be required for license renewal at the next renewal period after the licensee, by reciprocity, has been licensed one year in Oregon.

Stat. Auth.: ORS 689
Stats. Implemented: ORS 689.205
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04

855-021-0030
Continuing Pharmacy Education — Non-Resident — Dual Licensees

(1) Any Oregon licensed pharmacist residing in another state shall, in order to receive Oregon license renewal, meet Oregon requirements for continuing pharmacy education.

(2) The Board shall accept for CE credit programs for out of state pharmacists that have been approved by that state's Board of Pharmacy.

(3) Upon request, the Board may certify to another state's licensing authority the status of a licensee's continuing education participation in Oregon.

(4) The Board may request certification from another state's licensing authority regarding the status of an applicant's continuing education.

Stat. Auth.: ORS 435, 475 & 689
Stats. Implemented: ORS 689.205
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 10-1987, f. & ef. 12-8-87; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04

855-021-0045
Notification of Annual License Renewal

(1) The Board will develop an appropriate annual renewal notice to be mailed to all licensed pharmacists prior to May 1 of each year.

(2) The notice will state the annual pharmacist license fee and the continuing pharmacy education fee due for license renewal.

(3) The notice will include the continuing pharmacy education time requirement and any other information considered pertinent for the licensee's understanding of the renewal requirements.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.275
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02

855-021-0050
Renewal Application

(1) The annual renewal notice must be returned to the Board with the appropriate fee and the pharmacist must state that he/she has satisfactorily completed the continuing pharmacy education requirements by signing the renewal document.

(2) The Board may randomly select and audit applications for renewal to verify completion of the CE programs reported on the application for renewal. Pharmacists whose applications for renewal are selected for audit must provide documentation of completion of the CE programs reported. A pharmacist who fails to provide the requested documentation to the Board or who fails to complete the annual CE requirement may be disciplined for unprofessional conduct.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.275
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04

855-021-0055
Reinstatement

(1) Any petitioner for a reinstatement of a license after suspension, revocation, or refusal to renew as provided within ORS 689.445 shall produce certification of the continuing education requirement for all years in which the license has been suspended, revoked or not renewed prior to restoration of license.

(2) Retired pharmacists who wish to reinstate their license should refer to OAR 855-019-0040(2).

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979, f. & ef. 10-3-79, 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1981, f. & ef. 8-20-81

DIVISION 25

CERTIFIED PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-025-0001
Transition from Registration of Technician to Licensure of Technician

(1) Effective June 28, 2005, pharmacy technicians ceased to be registered and became licensed. As part of licensure, pharmacy technicians are now subject to disciplinary action by the Board and subject to specialized education and training requirements established by the Board. This rule provides a framework for the transition from registration to licensure.

(2) The existing Board file containing information on each registered pharmacy technician or applicant for registration as a pharmacy technician remains in effect when the registration program transitions to a licensure program. Pharmacy technicians and applicants need not resubmit application material or other information to the Board because of the transition to licensure unless the Board specifically requests resubmission. Complaints, investigations, renewal information, criminal history information and registration history information remain in effect and carry over into the licensing history for each pharmacy technician or applicant.

Stat. Auth.: 689.205
Stats. Implemented: 689.225
Hist.: BP 8-2005, f. 12-14-05, cert. ef. 12-15-05; BP 1-2006, f. & cert. ef. 6-9-06

855-025-0005
Qualifications for Licensure as a Pharmacy Technician or Certified Pharmacy Technician

(1) Effective August 1, 2006, to qualify for licensure as a certified pharmacy technician, an applicant must demonstrate that the applicant is or will be at least 18 years of age and holds or will hold a high school diploma or GED at the time the Board issues the license.

(2) No person whose license to practice as a pharmacist has been denied, revoked, suspended or restricted by the Board may be licensed as a pharmacy technician or certified pharmacy technician unless the Board determines that licensure will pose no danger to patients or to the public interest.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0010
Renewal of Licensure as a Pharmacy Technician Requires Certification

(1) The purpose of this rule is to ensure that all pharmacy technicians in Oregon become certified pharmacy technicians by passing a certification examination accepted by the Board. This rule requires all current pharmacy technicians to become certified by October 1, 2008, and gives all new pharmacy technicians until October 1, 2008, one year after initial licensure, or prior to the pharmacy technician's 19th birthday, whichever is later, to obtain certification.

(2) The license of a pharmacy technician expires one year from the date upon which it is issued, and may be renewed only if:

(a) The applicant has become certified by taking and passing one of the examinations described in section three or

(b) The applicant is less than 18 years of age.

(3) For any pharmacy technician license that expires on or after September 30, 2008, an applicant to renew a pharmacy technician license must demonstrate that the applicant for renewal has taken and passed the national pharmacy technician certification examination given by either:

(a) The Pharmacy Technician Certification Board (PTCB) or

(b) The Institute for the Certification of Pharmacy Technicians (ICPT).

(4) The license of a certified pharmacy technician expires on September 30 of each year and must be renewed annually.

(5) Notwithstanding any other provision of these rules, a pharmacy technician who is less than 18 years of age need not take and pass a certified pharmacy technician examination.

(6) Applicants for licensure or renewal of licensure as a pharmacy technician must submit to a criminal background check.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0015
Renewal of Licensure as a Certified Pharmacy Technician

(1) Licensed pharmacy technicians who have taken and passed a certification examination listed in OAR 855-025-0010(3) may use the title "certified pharmacy technician," are referred to in these rules as a "certified pharmacy technician," and are licensed as a "certified pharmacy technician."

(2) An applicant for renewal of a certified pharmacy technician license must:

(a) Maintain certification by one of the organizations listed in OAR 855-025-0010(3) and

(b) During each period from September 1 through August 31, complete and report at least one hour of pharmacy law, appropriate to the applicant's work setting and functions. Fifty minutes equal one contact hour.

(c) Submit to a criminal background check.

(3) The Board may randomly select and audit applications for renewal to verify completion of the continuing education reported on the application for renewal. Certified pharmacy technicians whose applications for renewal are selected for audit must provide documentation of completion of the continuing education reported.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0020
Recordkeeping Responsibilities of Pharmacy Technicians and Certified Pharmacy Technicians

(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.

(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(3) A pharmacy technician or certified pharmacy technician must report to the Board within 10 days if they:

(a) Are convicted of a misdemeanor or a felony; or

(b) If they are arrested for a felony.

(4) A pharmacy technician or certified pharmacy technician who has reasonable cause to believe that another licensee (of the Board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting pharmacy technician or certified pharmacy technician shall report the conduct without undue delay, but in no event later than 10 working days after the reporting pharmacy technician or certified pharmacy technician learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.

(5) A pharmacy technician or certified pharmacy technician who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.

(6) A pharmacy technician or certified pharmacy technician who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the Board within 10 days.

(7) A pharmacy technician or certified pharmacy technician must notify the Board in writing, within 15 days, of any change in employment location or residence address except that a technician who is

employed at more than one pharmacy need only report the name and address of the pharmacy at which the technician normally works the most hours.

(8) A certified pharmacy technician must obtain certificates of completion that show the date and number of hours earned to document continuing education credit earned and must keep the certificates of completion for three years from the date of the program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, Ch. 536 OL 2009
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 6-2010, f. & cert. ef. 6-29-10

855-025-0025
Use of Pharmacy Technicians and Certified Pharmacy Technicians

(1) A pharmacist or pharmacy may use pharmacy technicians and certified pharmacy technicians only as authorized by the rules of the Board.

(2) Pharmacy technicians and certified pharmacy technicians must be supervised by a pharmacist.

(3) Pharmacists, pharmacist interns, pharmacy technicians and certified pharmacy technicians must be clearly identified as such to the public.

(4) Work performed by pharmacy technicians and certified pharmacy technicians assisting the pharmacist to prepare medications must be verified by a pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.

(5) The pharmacist-in-charge must prepare and maintain in the pharmacy written procedures that describe the tasks performed by pharmacy technicians and certified pharmacy technicians, and the methods of verification and documentation of work performed by pharmacy technicians and certified pharmacy technicians. Written procedures must be available for inspection by the Board or its representatives. The pharmacist-in-charge must review written procedures annually and document that review on the annual pharmacist-in-charge inspection sheet.

(6) Training:

(a) The pharmacist-in charge must outline, and each pharmacy technician and certified pharmacy technician must complete initial training that includes on-the-job and related education commensurate with the tasks that the pharmacy technician or certified pharmacy technician will perform, prior to the performance of those tasks.

(b) The pharmacist-in-charge must ensure the continuing competency of pharmacy technicians and certified pharmacy technicians.

(c) The pharmacist-in-charge must document initial training of each pharmacy technician and certified pharmacy technician and make that documentation available to the Board or its representatives upon request.

(7) Upon written request, the Board may waive any of the requirements of this rule upon a showing that a waiver will further public health or safety or the health or safety of a patient or other person. A waiver granted under this section is effective only when issued by the Board in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0030
Confidentiality

(1) No licensee of the Board who obtains any patient information shall disclose that information to a third-party without the consent of the patient except as provided in section two of this rule.

(2) A licensee may disclose patient information:

(a) To the Board;

(b) To a practitioner, pharmacist, pharmacy technician, or certified pharmacy technician, if disclosure is authorized by a pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0035
Pharmacy and Pharmacist Responsibility for Supervising Pharmacy Technicians and Certified Pharmacy Technicians

(1) The supervising pharmacist and the pharmacist-in-charge are responsible for the actions of pharmacy technicians and certified pharmacy technicians. The use of pharmacy technicians or certified pharmacy technicians to perform tasks not included in written procedures maintained by the pharmacy constitutes unprofessional conduct on the part of the supervising pharmacist and the pharmacist-in-charge.

(2) The pharmacy must maintain on file and post the current license of each pharmacy technician and certified pharmacy technician.

(3) Before allowing any person to work as a pharmacy technician or certified pharmacy technician, the pharmacy and pharmacist shall verify that the person is currently licensed as a pharmacy technician or certified pharmacy technician.

(4) Prior to performing the duties of a pharmacy technician or a certified pharmacy technician, a person must provide to the pharmacist or pharmacist-in-charge a copy of the person's current pharmacy technician license or a current certified pharmacy technician license.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0040
Certified Pharmacy Technician and Pharmacy Technician Tasks and Guidelines

(1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the pharmacist.

(2) Only persons licensed with the Board as a Pharmacy Technician or Certified Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, may assist in the practice of pharmacy by the following:

(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Reconstituting prescription medications. The supervising pharmacist must verify the accuracy in all instances.

(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.

(d) Entering information into the pharmacy computer. The pharmacy technician or certified pharmacy technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.

(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;

(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.

(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The pharmacist must verify the accuracy of the finished task.

(h) Checking nursing units in a hospital or nursing home for non-judgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a pharmacist.

(i) Recording patient or medication information in computer systems for later verification by the pharmacist.

(j) Bulk Compounding. Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other

products for the pharmacy or other departments of a hospital. The supervising pharmacist must verify the accuracy in all instances.

(k) Preparation of parenteral products as follows:

(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising pharmacist must verify the accuracy in all instances.

(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising pharmacist must verify the accuracy in all instances.

(l) Performing related activities approved in writing by the Board.

(3) In order to protect the public, safety, health and welfare, pharmacy technicians or certified pharmacy technicians shall not:

(a) Communicate or accept by oral communication a new or transferred prescription of any nature;

(b) Receive or transfer a prescription to another pharmacy without the prior verification of a pharmacist.

(c) Provide a prescription or medication to a patient without a pharmacist's verification of the accuracy of the dispensed medication;

(d) Counsel a patient on medications or perform a drug utilization review;

(e) Perform any task that requires the professional judgment of a pharmacist; or

(f) Engage in the practice of pharmacy as defined in ORS 689.015.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

855-025-0050
Grounds for Discipline of Pharmacy Technicians and Certified Pharmacy Technicians

The State Board of Pharmacy may refuse to issue or renew; or may suspend, revoke, or restrict the license of a pharmacy technician or certified pharmacy technician; or may impose a civil penalty upon a pharmacy technician or certified pharmacy technician upon the following grounds including but not limited to:

(1) Unprofessional conduct as defined in OAR 855-006-0005;

(2) Repeated or gross negligence in performing the duties of a pharmacy technician or certified pharmacy technician;

(3) Impairment, which means an inability to assist in the practice of pharmacy with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;

(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;

(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;

(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;

(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a pharmacy technician or certified pharmacy technician license;

(8) Allowing an individual to engage in the duties of a pharmacist, pharmacy technician or certified pharmacy technician without a license or to use falsely the title of pharmacist, pharmacy technician or certified pharmacy technician;

(9) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto;

(10) Failure to appropriately perform the duties of a pharmacy technician or certified pharmacy technician as outlined in OAR 855-025-0040 while assisting a pharmacist in the practice of pharmacy as defined in ORS 689.005;

(11) Any act or practice relating to performing the duties of a pharmacy technician or certified pharmacy technician which is prohibited by state or federal law or regulation; or

(12) Any conduct or practice by a pharmacy technician, certified pharmacy technician or pharmacy that the Board determines is contrary to the accepted standards of practice.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, Ch. 756 OL 2009
Hist.: BP 9-2005, f. 12-14-05, cert. ef. 12-15-05; BP 1-2006, f. & cert. ef. 6-9-06; BP 6-2010, f. & cert. ef. 6-29-10

855-025-0060
Petition for Reinstatement of a Certified Pharmacy Technician License

(1) A certified pharmacy technician's license that has been revoked, suspended or restricted will be reinstated only if the Board finds, upon a presentation made by the petitioner, that there is a reasonable assurance that the public interest will be protected if relicensure occurs.

(2) A presentation must consist of a showing by the petitioner of changed circumstances from those surrounding the revocation, suspension or restriction of license. The presentation must include:

(a) A showing that the petitioner has engaged in treatment, programs, or other endeavors or activities since the suspension, revocation or restriction of license which has caused the rehabilitation of the petitioner to the extent that the public's interest would be protected if relicensure should be granted.

(b) Medical, psychological, sociological or other physical, mental or moral appraisals, evaluations or recommendations relating to the petitioner to aid the Board in its determination whether the petitioner has been rehabilitated to the extent that the public's interest would be protected if relicensure should be granted.

(3) Petitions to the Board for reinstatement of licensure after suspension, revocation or restriction must be in writing and must contain:

(a) A written statement of those changed circumstances which the petitioner believes warrant the Board's finding that there is a reasonable assurance that the public interest will be protected if relicensure occurs. Such statement must include a recitation of the treatment, programs, or other endeavors or activities undertaken by the petitioner, more particularly referred to subsection (2)(a) of this rule.

(b) A summarization of the medical, psychological, sociological or other physical, mental, or moral appraisals or recommendations which the petitioner intends to present to the Board pursuant to subsection (2)(b) of this rule.

(4) If, after opportunity is afforded the petitioner to show otherwise, the Board determines that a petition fails to comply with section (3) of this rule, or has not been made within a reasonable interval from the suspension, revocation, or restriction of license or from a previous petition, the Board will dismiss the petition without further investigation and hearing before the Board.

(5) Petitions which comply with section (3) of this rule will be scheduled for presentation of proof before the Board, and the petitioner will be notified of the time and place.

(6) The completion of any treatment, program or activity which the Board may recommend does not establish a right to reinstatement. The Board must, in each and every case, make a finding based upon the presentation of the petitioner that there is a reasonable assurance that the public interest will be protected if relicensure occurs.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06

DIVISION 31

INTERNSHIP REGULATIONS

855-031-0005
Definitions

(1) An "intern" means any person who:

(a) Is enrolled in a course of study and is in good academic standing at a school or college of pharmacy that is approved by the Oregon Board of Pharmacy (Board); or

(b) Is a graduate of a school or college of pharmacy that is approved by the Board; or

(c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC); and

(d) Is licensed with the Board as an intern.

(2) A "preceptor" means a pharmacist or a person licensed by the Board to supervise the internship training of an intern.

(3) "Internship" means a professional experiential program or work experience.

(a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving competency in the practice of pharmacy for which no academic credit is granted to the intern.

(b) "School-based Rotational Internship (SRI)" means experience toward achieving competency in the practice of pharmacy in programs developed and administered by a school of pharmacy.

(c) "Other Internship" means experience toward achieving competency in the practice of pharmacy, other than in an internship as defined in (a) or (b) , in a program approved by a school of pharmacy or the Board.

(4) "School of pharmacy": In this division of rules, "school of pharmacy" means a school or college of pharmacy that is approved by the Board.

Stat. Auth.: ORS 689.151 & 689.205
Stats. Implemented: 689.255
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; Administrative correction 2-15-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-031-0010
Internship License Application

(1) Applications for licensure as an intern may be obtained from the Board office or from the Board web site at www.pharmacy.state.or.us.

(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;

(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(2) The Board may issue a license to a qualified intern after the receipt of:

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110-0005;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Any fingerprint card or other documentation required by the Board to conduct a criminal background check; and

(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:

(A) Provide a copy of a valid visa permitting full-time employment;

(B) Provide the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and

(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT) with a minimum score of 26 in Speaking, 21 in Reading, 18 in Listening and 24 in Writing, however scores will be accepted until June 30, 2010 from candidates who have already passed or are scheduled to take the TOEFL and the Test of Spoken English (TSE).

(3) The Board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. For licenses issued after May 1, 2010, the initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events:

(a) Licensure to practice pharmacy is granted in any state; or

(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or

(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months;

(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program.

(4) An intern must surrender their license to the Board within 30 days of one of the above events.

(5) Notwithstanding the requirements of section (3) above, upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 689.151 & 689.205
Stats. Implemented: ORS 689.207, 689.255 & 2009 OL Ch. 536
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 1-1994, f. & cert. ef. 2-2-94; BP 1-2001, f. & cert. ef. 3-5-01; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-031-0020
Internship Requirements and Responsibilities

(1) A licensed intern may practice in any one or a combination of the following approved internship experience areas:

(a) Traditional Pharmacy-practice Internship (TPI); however, an intern may not work in a TPI until they have satisfactorily completed the first academic year in a school of pharmacy. An intern working in a TPI must be supervised by a licensed pharmacist;

(b) School-based Rotational Internship (SRI); an intern must be supervised by a licensed pharmacist or other person approved by a school of pharmacy in order to obtain credit for SRI hours;

(c) Other Internship; these internship experiences must be approved by the school of pharmacy and supervised by a person approved by the school or the Board.

(2) An intern may not work more than 48 hours per week in SRIs.

(3) An intern must verify that their preceptor is currently licensed with the Board.

(4) An intern may not work in the practice of pharmacy unless supervised by a licensed pharmacist, except when an intern is working in a federal facility, however, to obtain credit for SRI experience in a federal facility located in Oregon, the intern must be licensed with the Board.

(5) An intern who is working in a pharmacy or other place of business must conspicuously display their intern license in the pharmacy or place of business.

(6) The school of pharmacy must maintain a record of each intern's SRIs. This record must be made available to the Board upon request.

(7) A school of pharmacy located in Oregon must submit a report on their experiential education program to the Board at the end of each academic year. This report must include the names of students who successfully completed the program and graduated. The school must maintain a list of preceptors and SRI sites, in and out-of-state, approved by the school and must make this list available to the Board upon request.

(8) An intern may make a voluntary report to the Board on any preceptor's aptitude and professionalism in performing the duties of a preceptor. An intern must make such a report upon request by the Board.

(9) An intern must notify the Board within 15 days of any change in their academic status that might affect their eligibility to work as an intern.

(10) An intern must notify the Board in writing within 15 days of a change in permanent residence.

(11) An intern must report to the Board within 10 days if they are:

(a) Convicted of a misdemeanor or a felony; or

(b) Arrested for a felony.

(12) An intern who has reasonable cause to believe that another licensee (of the Board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The intern shall report the conduct without undue delay, but in no event later than 10 working days after the intern learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.

Stat. Auth.: ORS 689.151, 689.205
Stats. Implemented: 689.255 & 2009 OL Ch. 536
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1994, f. & cert. ef. 2-2-94; PB 3-1994, f. & cert. ef. 7-1-94; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-031-0030
Out-of-State Internship Experience

(1) In order for an Oregon intern to obtain credit for SRI experiences outside the State of Oregon, an intern must:

(a) Be licensed as required by state laws and rules in the state in which they will practice;

(b) Meet or exceed the minimum SRI requirements of the Board;

(2) In order for an out-of-state intern to practice in the State of Oregon, the intern must meet all requirements of these rules.

Stat. Auth.: ORS 689.151 & 689.205
Stats. Implemented: 689.255
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 1-1994, f. & cert. ef. 2-2-94; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-031-0045
Preceptor Registration and Responsibilities

(1) A preceptor license may be issued by the Board upon receipt of a completed application.

(2) A pharmacist preceptor must have been an actively practicing pharmacist for at least one year immediately prior to supervising an intern.

(3) A preceptor license must be renewed concurrent with licensure as a pharmacist and is valid through June 30.

(4) The preceptor may report to the Board voluntarily, the progress and aptitude of an intern under the preceptor's supervision, or must do so upon request of the Board.

(5) The preceptor must be responsible for supervision of the majority of the intern's SRI hours and must provide the intern with internship experiences, which in the preceptor's judgment will increase the intern's competency in the practice of pharmacy.

(6) A preceptor must maintain written or electronic records that support the number of TPI hours claimed by an intern while under their supervision. Such records must be retained for three years and made available to the Board upon request.

(7) Before supervising an intern in an SRI program, a preceptor must complete any training program required by the school of pharmacy.

(8) A pharmacist must not supervise more than one intern simultaneously at a TPI site.

(9) A preceptor must not supervise more than two interns simultaneously at an SRI site where patient specific recommendations for care, or medications are provided without prior written approval of the Board.

(10) Notwithstanding section (9) above, with the approval of a school of pharmacy, and when in their professional judgment it is appropriate, a preceptor may supervise up to 10 interns at public-health outreach programs such as health fairs which provide general information but not direct patient care.

(11) A preceptor must advise each school of pharmacy when they are supervising students from more than one school at the same time. This applies to both in-state and out-of-state schools or colleges of pharmacy.

(12) A preceptor must verify that their intern is currently licensed with the Board.

(13) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a pharmacist in Oregon, but is required to be licensed as a preceptor with the Board.

Stat. Auth.: ORS 689.151, 689.205
Stats. Implemented: 689.255
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2004, f. & cert. ef. 3-12-04; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-031-0050
Eligibility for Exams — Foreign Pharmacy Graduates

In addition to the other requirements of this Division, a foreign pharmacy graduate must complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR 855-019-0150. Evidence of completing this requirement must be provided to the Board by the applicant and must be authenticated by each preceptor.

Stat. Auth.: ORS 689.151 & 689.205
Stats. Implemented: 689.255
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 5-1990, f. & cert. ef. 4-12-90; PB 7-1990, f. & cert. ef. 12-5-90; PB 1-1994, f. & cert. ef. 2-2-94; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-031-0055
Eligibility for Exams and Pharmacist Licensure

(1) An intern is eligible to take the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, upon graduation and notification to the Board by the school of pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.

(2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in the State of Oregon, a person must:

(a) Complete an application for licensure including providing any fingerprint card or other documentation required by the Board to conduct a criminal background check;

(b) Pay the license fee as prescribed in OAR 855-110; and

(c) Obtain a license, which will expire on June 30 following the date of issue.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135, 689.207, 689.225 & 689.275
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89; PB 5-1990, f. & cert. ef. 4-12-90; PB 7-1990, f. & cert. ef. 12-5-90; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

DIVISION 35

OPERATION OF NONPRESCRIPTION AND MEDICAL DEVICE, EQUIPMENT AND GAS (MDEG) OUTLETS

855-035-0005
Applications

(1) All applications for registration of a new or relocated proprietary drug outlet shall be accompanied by the required fees as set forth in 855-110-0007.

(2) Application shall specify the location of the proprietary drug outlet. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(c) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(3) All registration renewal applications shall be accompanied by the annual fee and contain the same information required in subsections (2)(a), (b) and (c) of this rule.

(4) If the annual registration fee referred to in section (1) of this rule is not paid by January 31 of the current year, a delinquent fee as set forth in OAR 855-110-0007 shall be included with the application for registration renewal.

(5) A change of ownership or location requires a new application, fee and registration within 15 days of the change .

(6) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(7) The registration fee cannot be prorated.

(8) No nonprescription drug or medical gas authorized to be sold at retail under this registration shall be sold, given away, or otherwise disposed of until application has been approved and a certificate of registration issued. There shall be four types of drug outlet registrations:

(a) Class A shall be for all outlets except those that own more than one vending machine distributing more than six nonprescription drugs.

(b) Class B shall be for all outlets except those that own more than one vending machine distributing six or less nonprescription drugs.

(c) Class C shall be for all outlets distributing medicinal gases.

(d) Class D shall be for all outlets with more than one vending machine distributing nonprescription drugs.

(e) Class E shall be for any nonprofit, tax exempt, food distribution facility that distributes food products and nonprescription drugs at no cost, other than nominal delivery charges, to charitable organizations including regional food banks, for distribution at no cost to individuals. This registration, which shall be issued at no cost to the registrant, expires on January 31st annually.

Explanation: The intention of this section is that an owner of a single vending machine that contains over-the-counter medications can register as either a Class A or Class B outlet based on the number of medications in the machine. The owner of more than one vending machine that contains over-the-counter medications shall register as a Class D outlet and inform the Board of their locations. Class E registration is intended for the Oregon Food Bank and other regional food banks located in Oregon.

(9) If there is more than one drug outlet under the same roof and each outlet is independently operated by different owners, a separate registration shall be obtained for each outlet.

(10) In case of loss of the certificate of registration, the Board may require a sworn statement before a notary public to be filed in the Board office before duplicate certificates of registration can be issued.

(11) Each vending machine that contains nonprescription drugs must have an obvious and legible statement on the machine that identifies the owner of the machine, advises the customer to check the expiration date of the product before using, and lists the phone number for the Board of Pharmacy.

(12) A Class D nonprescription drug outlet shall keep the Board informed in writing of the current location of all of its vending machines.

(13) Notwithstanding the requirements of this rule and the other rules in this Division, upon written request the Board may waive any of the requirements of this rule or the other rules in this Division if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented: ORS 475.035, 689.135 & 689.305
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 2-2008, f. & cert. ef. 2-20-08

855-035-0007
Sales

Sales by drug outlets except itinerant vendors shall be made only from the premises at the location registered by the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.305, 689.315 & 689.325
Hist.:. 1PB 2-1981, f. & ef. 8-20-81; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96

855-035-0010
Minimum Standards for Nonprescription and Medical Gas Drug Outlets

(1) Drug outlets shall have floor space and shelving to insure that drugs are stocked and stored in sanitary, well-lighted areas. Where applicable, temperature, ventilation and moisture controls shall be employed.

(2) Expiration dates on drug outlet drugs shall be the responsibility of each drug outlet to insure products are in date.

(3) There shall be no advertisements of any kind by a drug outlet using the following or similar terms: "drug store," "pharmacy," "apothecary."

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.305 & 689.325
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96

855-035-0015
Change of Business Name, Closure

(1) Any change of business name of a drug outlet must be reported to the Board within 15 days by filing a new application for which no fee is required. New certificates of registration will be issued at the next regular renewal period.

(2) Any closure of a drug outlet shall be reported to the Board within 15 days.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.325
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1996, f. & cert. ef. 4-5-96

855-035-0020
Sales of Non-Prescription Drugs

Registered nonprescription drug outlets may sell or donate nonprescription drugs in the original and unbroken packages only, properly labeled according to state and federal law, in conformity with rules of the Board. A nonprescription drug outlet shall not purchase or receive nonprescription drugs from a source not registered with the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.135, 689.305 689.315
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96; BP 2-2008, f. & cert. ef. 2-20-08

855-035-0023
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1992, f. & cert. ef. 1-31-92

855-035-0025
Seasonal Nonprescription Drug Outlets

(1) Seasonal nonprescription drug outlets are defined as those outlets who either by location or weather are restricted to a seasonal demand for services.

(2) Seasonal nonprescription drug outlets shall be exempt from delinquent fees for nonprescription registration if renewals are paid no later than June 1 of current year.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.325
Hist.: 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96

855-035-0030
Medical Device, Equipment and Gas (MDEG) Outlet (Class C)

(1) Medical Device, Equipment and Gas (MDEG) Outlets may sell:

(a) Nonprescription drugs;

(b) Specific drugs and materials that require the order or prescription of a practitioner:

(A) USP Oxygen;
(B) USP Sodium Chloride Irrigation;
(C) USP Sodium Chloride Injection;
(D) Sterile water for irrigation;
(E) Urological catheters; and
(F) Respiratory devices.

(2) Medicinal Gas Drug Outlets shall distribute medicinal Nitrous Oxide only to practitioners or institutional drug outlets.

(3) Record keeping: All records of receipt and distribution of medical devices, equipment, and gas must be maintained for a minimum of three years and must be readily retrievable.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02

DIVISION 41

OPERATION OF PHARMACIES (RETAIL AND INSTITUTIONAL DRUG OUTLETS) CONSULTING PHARMACISTS AND OPERATION OF DRUG ROOMS

855-041-0005
Pharmacy Registration (Both Retail and Institutional Drug Outlets)

(1) Pharmacies shall be registered as either retail drug outlets or institutional drug outlets or both.

(2) An application for registration of a new pharmacy shall be accompanied by a floor plan drawn to scale and shall be approved by the Board prior to opening.

(3) The application shall specify the location of the pharmacy and shall indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy,

the application shall indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests shall be indicated on the application;

(b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(4) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(5) The application shall also identify any person who has incidents of ownership in the pharmacy who also has financial interest in any long-term care facility as defined in ORS 442.015.

(6) A certificate of registration will be issued upon Board approval of the application.

(7) All registration renewal applications shall be accompanied by the annual fee and shall contain the same information required in sections (3) and (4) of this rule.

(8) The initial and annual registration fee for pharmacies is set out in division 110 of this chapter.

(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to in section (7) of this rule is not paid by March 31 of the current year, a delinquent fee as set out in division 110 of this chapter shall be included with the application for registration renewal.

(10) The registration is not transferable and the registration fee cannot be prorated.

(11) A change of ownership requires the approval of the Board and new certificate of registration. Application shall be on a form supplied by the Board.

(12) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(13) Applicants for change in ownership shall provide the Board with the information required in sections (3), (4), and (5) of this rule.

(14) Following Board approval a change of ownership shall be reported to the Board within 15 days of the occurrence.

(15) No pharmacy shall be operated until a certificate of registration has been issued to the pharmacy by the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 5-1990, f. & cert. ef. 4-12-90; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94

855-041-0007
Applicability of Rules

(1) In conjunction with the rules in division 19 of this chapter, these rules, OAR 855-041-0015 through 855-041-0620 apply to all retail and institutional drug outlets doing business in Oregon, and to the pharmacists working in these outlets.

(2) The provisions of OAR 855-041-0015 through 855-041-0100 are applicable to all retail drug outlets, including the practice of pharmacy in such outlets, and are applicable to all institutional drug outlets except where OAR 855-041-0105 through 855-041-0160 provide specific exemption or exceptions or where 855-041-0105 through 855-041-0160 are in direct conflict in which case 855-041-0105 through 855-041-0160 shall apply.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.305
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89; Renumbered from 855-041-0050, BP 2-2008, f. & cert. ef. 2-20-08

855-041-0010
Change of Location of a Pharmacy (Both Retail and Institutional Drug Outlets)

(1) A change of location of a pharmacy requires the approval of the Board and a new certificate of registration.

(2) Application for approval to relocate shall be on a form provided by the Board and shall be accompanied by fees and a floor plan drawn to scale.

(3) A certificate of registration will be issued upon Board approval of the application.

(4) Following Board approval, a change of location, shall be reported to the Board within 15 days of the occurrence.

(5) No pharmacy shall be operated until a certificate of registration has been issued to the pharmacy by the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 5-1990, f. & cert. ef. 4-12-90; PB 1-1994, f. & cert. ef. 2-2-94

855-041-0015
Change of Business Name, Closure (Both Retail and Institutional Drug Outlets)

(1) Any change of business name of a pharmacy must be reported to the Board within 15 days by filing a new application for which no fee is required. New certificates of registration will be issued at the next regular renewal period.

(2) Any closure of a pharmacy shall be reported to the Board within 15 days and include notification of the disposition of controlled substances, dangerous, legend, and restricted drugs.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94

855-041-0017
Pharmacy Advertising

No person shall advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the Board pursuant to ORS 689.305.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92)

855-041-0020
Personnel (Both Retail and Institutional Drug Outlets)

(1) Each pharmacy must have one pharmacist-in-charge employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.

(2) The pharmacy must ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in conformance with the keeping and inventory requirements of federal law and board rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.305
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1986, f. & ef. 12-8-86; PB 10-1987, f. & ef. 12-8-87; PB 9-1989, f. & cert. ef. 7-20-89; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2001, f. & cert. ef. 3-5-01; BP 2-2008, f. & cert. ef. 2-20-08

855-041-0025
Operation of Pharmacy (Both Retail and Institutional Drug Outlets)

(1) **Supervision**. A pharmacy may only be operated when a pharmacist licensed to practice in this state is present. This means that the pharmacist must be physically present in the pharmacy or institutional facility.

(2) **Sanitation**:

(a) Pharmacies shall be kept clean.

(b) Persons working in a pharmacy shall practice appropriate infection control.

Stat. Auth.: ORS 689.305
Stats. Implemented: ORS 689.305
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 12-1989, f. & cert. ef. 8-11-89; PB 1-1997, f. & cert. ef. 9-22-97

855-041-0026
Security of Prescription Area

(1) The area in a registered pharmacy where legend and/or controlled substances are stored, possessed, prepared, manufactured, compounded, or repackaged shall be restricted in access, in such a manner as to insure the security of those drugs.

(2) The pharmacist-in-charge and each pharmacist while on duty shall be responsible for the security of the prescription area including

provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.

(3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-pharmacist employees or owners to have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041-0035.

(4) Prescription drugs and devices and non-prescription Schedule V controlled substances shall be stored within the prescription area or a secured storage area.

(5) Any security system deviating from the requirements of this section, except as provided in OAR 855-041-0120, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such security system, as approved by the Board, shall be maintained in the pharmacy.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 5-1982, f. & ef. 8-6-82; PB 1-1987, f. & ef. 2-3-87

855-041-0030
Loss of Pharmacy Certificate of Registration (Both Retail and Institutional)

In case of loss of certificate of registration, the Board may require a sworn statement before a notary public to be filed in the Board office before duplicate certificates of registration can be issued.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-041-0035
Operation of a Double Set-Up Pharmacy in a Retail Drug Outlet

A double set-up is an establishment having both a retail drug outlet registration and a nonprescription drug outlet registration. In a double set-up:

(1) The retail drug outlet (pharmacy) must be a separate operation, completely contained by an enclosure which assures safe storage. This enclosure must be from floor to ceiling or be at least ten feet from the floor. This area is to be easily distinguished by the public. When the retail drug outlet (pharmacy department) is closed, then as a nonprescription drug outlet the establishment is subject to the provisions of OAR 855-035-0005 and 855-035-0020.

(2) When a pharmacist is not in attendance, a closed sign shall be posted at the entrances stating the hours of the pharmacy's operation. All entrances to the retail drug outlet shall be closed off and securely locked. Any keys to the retail drug outlet (pharmacy) shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge if the retail drug outlet (pharmacy) is closed while the nonprescription outlet (shopkeeper) remains open.

(3) Any system deviating from the requirement of this section, except as provided in OAR 855-041-0120, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such system, as approved by the Board, shall be maintained in the pharmacy.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89; Administrative correction 9-8-97

855-041-0036
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1990, f. & cert. ef. 1-23-90; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92)

855-041-0037
Reporting Drug Loss

(1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices shall immediately be reported to the Board.

(2) When there are reasonable grounds to believe that drugs have been stolen, the pharmacist shall immediately notify the Board.

(3) At the time a Report of Theft or Loss of Controlled Substances (D.E.A. Form 106) is sent to the Drug Enforcement Administration, a copy shall bent to the Board. When loss of controlled substances is due to burglary or robbery, a copy of the police report shall be sent to the Board.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: 1PB 2-1981, f. & ef. 8-20-81; 1PB 1-1986, f. & ef. 6-5-86; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92)

855-041-0040
Minimum Equipment Requirements (Both Retail and Institutional Drug Outlets)

The minimum equipment requirement to open and operate a retail drug outlet and institutional drug outlet in the state of Oregon shall consist of not less than the following:

(1) The most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(2) Current and properly filed Oregon Revised Statutes, Chapters 689, and 475; current and properly filed Oregon Administrative Rules, chapter 855; and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in house or other readily retrievable means.

(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.

(4) Suitable refrigeration.

(5) A sink with running hot and cold water.

(6) Equipment and supplies appropriate to and based on the standards of practice for the setting as determined by the Pharmacy and Pharmacist-in-Charge.

(7) Failure to have and use equipment necessary to your practice setting constitutes unprofessional conduct for purposes of ORS 689.405(1)(a).

(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions. Exceptions to the above list may be approved by the Board of Pharmacy.

Stat. Auth.:ORS 689.205 & 689.508
Stats. Implemented: ORS 689.205 & 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; 1PB 4-1986, f. & ef. 12-8-86; PB 8-1987, f. & ef. 9-30-87; PB 12-1989, f. & cert. ef. 8-11-89; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; BP 3-2005, f. & cert. ef. 4-14-05

855-041-0055
New Containers

In filling the original prescriptions, nothing but new containers may be used. A patient's original container may be refilled if clean and the label is legible and up-to-date. The container shall comply with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations adopted thereunder. It must also conform with the current **United States Pharmacopoeia/National Formulary** monographs for preservation, packaging, storage and labeling.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-041-0056
Defines Labeling and Container Requirements for Repackage Drugs

(1) Drugs prepackaged by a pharmacy for later own use dispensing on prescription shall be in a container meeting USP standards and labeled to identify at a minimum:

(a) Brand name, or generic name and manufacturer;

(b) Strength;

(c) Lot number;

(d) Manufacturer's expiration date, or any earlier date which, in the pharmacist's professional judgment, is preferable.

(2) An internal control number which references manufacturer and lot number may be utilized.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 6-1987, f. & ef. 5-1-87

855-041-0057
Customized Patient Medication Packages

In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak). A patient med pak is a package prepared by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med pak is so designed for each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken:

(1) *Label*:

(a) The patient med pak shall bear a label stating:

(A) The name of the patient;

(B) A serial number for each patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

(C) The name, strength, physical description or identification, and total quantity of each drug product contained therein;

(D) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;

(E) Any storage instructions or cautionary statements required by the official compedia;

(F) The name of the prescriber of each drug product;

(G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be no later than 60 days from the date of preparation);

(H) The name, address, and telephone number of the dispenser and the dispenser's registration number where necessary; and

(I) Any other information, statements, or warnings required for any of the drug products contained therein.

(b) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug products contained therein.

(2) *Labeling*: The patient med pak shall be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med pak.

(3) *Packaging*:

(a) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak shall comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened;

(b) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician, to dispense in a container not intended to be child-resistant, shall be obtained.

(4) *Guidelines*: It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.

(5) *Recordkeeping*: In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, as a minimum:

(a) The name and address of the patient;

(b) The serial number of the prescription order for each drug product contained therein;

(c) The name of the manufacturer or labeler and lot number for each drug product contained therein;

(d) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

(e) The date of preparation of the patient med pak and the beyond-use date that was assigned;

(f) Any special labeling instructions; and

(g) The name or initials of the pharmacist who prepared the patient med pak.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 1-1989, f. & cert. ef. 1-3-89

855-041-0060
Prescription Records and Retention

(1) Definitions. The following definitions apply to this rule:

(a) An "original prescription" is a prescription maintained in the same physical manner in which a pharmacy first receives the prescription. For example, for a prescription received by the pharmacy in writing on a prescription form, the original prescription consists of the original writing on the prescription form. For a prescription received by the pharmacy orally over the telephone, the original consists of the writing or electronic record that reflects receipt of the oral prescription.

(b) "Filing" and "file" mean the storage of the original prescription in such a manner that the original prescription is safeguarded and readily retrievable.

(2) Every pharmacy and pharmacist-in-charge of a pharmacy must ensure that original prescriptions are properly filed in compliance with this rule.

(3) All original prescriptions shall be filed for a minimum of three years from the date of first dispensing and shall at all times be open for inspection by the prescriber, and the Board of Pharmacy or its duly authorized agent.

(4) After 120 days, the paper prescription may be destroyed and filed in an electronic form if:

(a) The electronic form shows the exact and legible image of the original prescription;

(b) Notes of clarifications of and changes to the prescription are directly associated with the electronic form of the prescriptions; and

(c) The prescription is not for a controlled substance.

(5) A patient record system shall be maintained by pharmacies for all patients for whom prescription drug orders are dispensed, except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs. The patient record system shall provide for readily retrievable information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(a) Full name of the patient for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) Chronic medical conditions;

(f) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(g) Known allergies, drug reactions, and drug idiosyncrasies; and

(h) If deemed relevant in the pharmacist's professional judgment:

(A) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(B) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

(6) Patient records shall be maintained for a period of not less than three years.

(7) Drug Outlet Procedures:

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

(a) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

(b) Performing mandatory prospective drug utilization reviews;

(c) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;

(d) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

(e) Ensuring the delivery of each completed prescription to the correct party;

(f) Providing appropriate confidential professional advice concerning medications to patients or their agents;

(g) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties.

(8) This rule is not intended to alter or supersede the record-keeping requirements of any other federal or Oregon statute or rule, including but not limited to ORS 689.508, OAR 855-041-0065, and rules related to records for prescriptions for controlled substances.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; BP 3-2005, f. & cert. ef. 4-14-05; BP 2-2008, f. & cert. ef. 2-20-08

855-041-0061
Tamper-resistant Prescription

When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" shall have the meaning as defined in OAR 855-006-0015.

Stat. Auth.: 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2007(Temp), f. & cert. ef. 8-27-07 thru 2-18-08; BP 1-2008, f. & cert. ef. 2-5-08

855-041-0065
Requirements for Prescriptions — Prescription Refills

Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(1) Each pharmacy must document the following information:

(a) The name of the patient for whom, or the owner of the animal for which, the drug is dispensed;

(b) The full name and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner or other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

(c) If the prescription is for an animal, the species of the animal for which the drug is prescribed;

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(e) The directions for use, if given by the practitioner;

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner; and

(g) One of the following phrases or notations, in the prescribing practitioner's handwriting or, if the prohibition was communicated by telephone, the pharmacist's handwriting, if the practitioner wishes to prohibit the substitution of a brand name drug specified in the prescription:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); and

(G) Words with similar meaning.

(2) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III and IV are limited to five refills or six months from date of issue, whichever comes first.

(3) If the practitioner is not available and in the professional judgment of the pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner shall be promptly notified of the emergency refill.

(4) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include.

(a) The identity of the responsible pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

(5) After two years from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber. When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year. When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first. When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed two years. The prescription shall not be refilled out of context with the approximate dosage schedule unless specifically authorized by the prescriber. A "non-controlled substance" means those drugs defined as "legend" pursuant to ORS 689.005(29) but does not include those drugs or substances controlled under the jurisdiction of the United States Department of Justice Drug Enforcement Administration.

(6) Prescriptions must be labeled with the following information:

(a) Name, address and telephone number of the pharmacy;

(b) Date;

(c) Identifying number;

(d) Name of patient;

(e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label shall also contain the name of the manufacturer or distributor;

(f) Directions for use by the patient;

(g) Name of practitioner;

(h) Required precautionary information regarding controlled substances;

(i) Such other and further accessory cautionary information as required for patient safety;

(j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the pharmacist's professional judgement, a shorter expiration date is warranted. Any drug bearing an expiration date shall not be dispensed beyond the said expiration date of the drug; and

(k) After July 1, 2000, any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules. Between the implementation date of July 1, 2000, and June 30, 2002, the Board will not take formal disciplinary action against a licensee or registrant for failure to achieve full compliance with this rule. During this period, the Board will issue a letter of noncompliance requiring a response as to the reason(s) for the failure to comply and the plan to reach compliance. A letter of noncompliance will not be considered a disciplinary action, nor will it initiate or affect any other disciplinary action. Failure to respond to a letter of noncompliance or failure to demonstrate a good faith effort to comply may result in disciplinary action.

(7) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.505
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; 1PB 1-1986, f. & ef. 6-5-86; PB 8-1987, f. & ef. 9-30-87; PB 10-1989, f. & cert. ef. 7-20-89; PB 1-1991, f. & cert. ef. 1-24-91; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 3-1997(Temp), f. & cert. ef. 11-12-97; BP 1-1998(Temp), f. & cert. ef. 1-27-98 thru 5-4-98; BP 2-1998, f. & cert. ef. 3-23-98; BP 2-1999(Temp), f. & cert.

ef. 8-9-99 thru 1-17-00; BP 2-2000, f. & cert. ef. 2-16-00; BP 3-2000, f. & cert. ef. 2-16-00; BP 6-2000, f. & cert. ef. 6-29-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03

855-041-0075
Transfer of Prescription Information Between Pharmacies

(1) Prescriptions may be transferred between pharmacies for the purpose of refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1982, f. & ef. 3-8-82; 1PB 1-1986, f. & ef. 6-5-86; PB 2-1990, f. & cert. ef. 2-9-90; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); BP 2-1998, f. & cert. ef. 3-23-98; BP 6-2000, f. & cert. ef. 6-29-00

855-041-0080
Returned Drugs and Devices

(1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

(2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been removed from the pharmacy only if;

(a) The drugs or devices are accepted for destruction or disposal and;

(b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or device recall; or

(c) After consultation, a pharmacist determines that, in the pharmacist's professional judgment, harm could result to the public or a patient if the drugs or devices were not accepted for return.

(3) Not withstanding section 2 of this rule, drugs or devices previously dispensed or distributed may be returned and redispensed or redistributed provided all the following conditions are met:

(a) The drug is in an unopened, tamper-evident unit;

(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;

(c) The drug or device has not been adulterated or misbranded and has been stored under conditions meeting United States Pharmacopeia standards.

(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; PB 5-1989, f. & cert. ef. 1-30-89; PB 8-1990, f. & cert. ef. 12-5-90; BP 2-2006, f. & cert. ef. 6-9-06

855-041-0086
Verification of Prescription Authenticity

Alteration of a written prescription, other than by a pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 2-2008, f. & cert. ef. 2-20-08

855-041-0095
Pharmacy Depots

No licensed pharmacist shall participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. This shall apply to the prescription order blank and to the completed prescription medication container. Provided, however, that nothing in this rule shall prohibit a licensed pharmacist or a licensed pharmacy by means of its employee or by use of a common carrier, from picking up prescriptions, or delivering prescriptions, at the office or home of the prescriber, at the residence of the patient, or at the hospital or medical care facility in which a patient is confined.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-041-0103
Confidentiality

(1) No licensee or registrant of the Board who obtains any patient information shall disclose that information to a third party without the consent of the patient.

(2) Section (1) of this rule does not apply to:

(a) Any disclosure made to the Board;

(b) Any disclosure made to a practitioner or to another pharmacist when the pharmacist reasonably believes that disclosing such information is necessary to protect the patient's health or well being; or

(c) To a third party when disclosure is otherwise authorized or required by law.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented:
Hist.: PB 5-1992, f. & cert. ef. 10-23-92

Institutional Drug Outlets

855-041-0105
Definitions

For purposes of these rules, OAR 855-041-0105 through 855-041-0160, the following definitions apply:

(1) "Institutional Facility" means a hospital or other health care facility which is an inpatient care facility referred to in ORS 442.015, which includes long-term care facilities and special inpatient care facilities, and such facility is licensed by the appropriate state agency.

(2) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an institutional facility, and which is:

(a) Located within the institutional facility;

(b) Located outside the facility but provides pharmaceutical services to institutionalized patients.

(3) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have a pharmacy.

(4) "Pharmaceutical Service" means the control of the utilization of drugs, biologicals and chemicals including procuring, manufacturing, compounding, dispensing, distribution and storing of drugs, biologicals and chemicals under the conditions prescribed by this rule. The provision of drug information to patients and to other health professionals is included within the meaning of pharmaceutical services.

(5) "Supervision" means stationed within the same work area, coupled with the ability to control and be responsible for an action.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90

855-041-0110
Applicability of Rules

The provisions of OAR 855-041-0005 through 855-041-0100 are applicable to all retail drug outlets and are applicable to all institutional drug outlets except where OAR 855-041-0105 through 855-041-0160 provide specific exemptions or exceptions or where OAR 855-041-0105 through 855-041-0160 are in direct conflict, in which case OAR 855-041-0105 through 855-041-0160 shall apply.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89

855-041-0115
Registration

All institutional drug outlets shall register annually with the Board of Pharmacy. Institutional drug outlets which also provide outpatient pharmacy services shall also register as retail drug outlets.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80

Hospitals with Drug Rooms

855-041-0135
Supervision of Consulting Pharmacist

(1) In a hospital having a drug room and no pharmacy, the drug room must be supervised by a licensed pharmacist who provides his or her services with sufficient professionalism, quality and availability to adequately protect the safety of the patients and to properly serve the needs of the facility. The arrangements for a consulting pharmacist shall be in writing, and shall, at a minimum, provide that:

(a) The pharmacist is to act in the capacity of a part-time director;

(b) The pharmacist shall provide on-call service at all times;

(c) Adequate storage facilities for drugs will be provided; and

(d) All drugs supplies shall be labeled so as to insure that recalls can be effected and that proper control and supervision of such drugs may be exercised.

(2) One registered nurse supervisor and only one in any given shift may have access to the drug room and may remove drugs therefrom, except in an emergency situation. In that case, such nurse may designate another licensed nurse to obtain the required drug(s). Any access to the drug room deviating from the requirements of this section must be approved by the Board prior to implementation. The registered nurse supervisor shall be designated in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the drug room, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:

(a) Drugs can only be removed from the drug room on a practitioner's written order, or verbal order which has been reduced to writing;

(b) A log of drugs withdrawn from a drug room shall be maintained and initialed by the registered nurse;

(c) Drugs shall be removed for outpatients only in compliance with section (3) of this rule.

(3) The consultant pharmacist who is the part-time director of pharmaceutical services shall in concert with the appropriate committee of the hospital medical staff, develop policies and procedures which shall be implemented to provide emergency pharmaceuticals to outpatients during the hours when normal community or hospital pharmacy services are not available. Such policies shall allow the designated registered nurse supervisor to issue medications pursuant to the pharmacist's standing orders, which shall provide:

(a) A written order of a practitioner authorized to prescribe a drug is presented;

(b) The medication is prepackaged by a pharmacist and contains:

(A) Name, address and telephone number of the hospital;

(B) Name of drug, strength, and number of units; when a generic name is used, the label shall also contain the name of the manufacturer or distributor;

(C) Required precautionary information regarding controlled substances;

(D) Such other and further accessory cautionary information as required for patient safety;

(E) An expiration date after which the patient should not use the medication.

(c) No more than a 24-hour supply is provided to the patient, except when the pharmacist has informed the nurse supervisor that normal services will not be available within 24 hours;

(d) The container is labeled by the nurse supervisor before presenting to the patient, and shows the following:

(A) Name of patient;

(B) Directions for use to the patient;

(C) Date;

(D) Identifying number;

(E) Name of prescribing practitioner;

(F) Initials of the supervisor.

(e) The original written order by the prescriber is retained for verification by the pharmacist after completion by the nurse supervisor and shall bear:

(A) Name and address of patient;

(B) Date of issuance;

(C) Units issued;

(D) Initials of supervisor issuing medication.

(f) The original written order is verified by the pharmacist, initialed, dated, and filed in a separate location for a period of three years for Board inspection;

(g) The withdrawal of a single dose for immediate administration to the patient need not follow the requirements of subsection (d) of this section.

(4) Emergency Kits:

(a) Emergency Kit Drugs Defined. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of in-patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source;

(b) Supplying Pharmacist. All emergency kit drugs shall be prepared by a licensed pharmacist;

(c) Drugs Included. The director of pharmacy and the medical staff of the hospital shall jointly determine and prepare a list of drugs, by identity and quantity, in amounts sufficient for immediate therapeutic requirements, to be included in emergency kits. Such list of drugs shall be reviewed annually by the appropriate medical staff committee;

(d) Storage. Emergency kits shall be stored in areas to prevent unauthorized access and to insure a proper environment for preservation of the drugs within them, as required in official compendia;

(e) Labeling — Interior. All drugs contained in emergency kits shall be labeled in accordance with OAR 855-041-0130(7);

(f) Labeling — Exterior. The exterior of emergency kits shall be labeled to clearly and unmistakable indicate that is is an emergency drug kit and it is for use in emergencies only; such label shall also contain a listing of the name, strength and quantity of the drugs contained therein and an expiration date;

(g) Expiration Date. The expiration date of an emergency kit shall be the earliest expiration date on any drug supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall open the kit and replace expired drugs;

(h) Removal of Drugs. Drugs shall be removed from emergency kits by authorized personnel only pursuant to a valid order or by the supplying pharmacist;

(i) Notifications. Whenever an emergency kit is opened or has expired, the supplying pharmacist shall be notified and the pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 3-1979(Temp), f. & ef. 10-31-79; 1PB 2-1980, f. & ef. 4-3-80; PB 12-1989, f. & cert. ef. 8-11-89

855-041-0140
Drug Distribution and Control from a Drug Room in a Hospital

(1) General. The director of pharmacy shall establish and implement written procedures for the safe and efficient distribution of pharmaceutical products. An annually updated copy of such procedures shall be available for inspection by the Board.

(2) Availability. A pharmacist providing pharmaceutical services to a hospital maintaining a drug room shall be engaged by the hospital and shall schedule on-premises visits on at least a weekly basis.

(3) Span of Control. The pharmacist's span of supervision shall extend to all areas of the hospital where drugs are stored. No less than every two months inspections of these areas shall be conducted and substantiated by records so as to verify at least proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the required emergency drug supply.

(4) Director's Absence. In the absence of the director of the pharmaceutical service, pharmaceutical services shall be directed by a designated pharmacist.

(5) Responsibility. The director of pharmacy shall be responsible for procedures for the safe and efficient distribution of, control of and accountability for drugs. Accordingly, the director shall be responsible for, at a minimum, the following:

(a) Procedures for preparation and sterilization of parenteral medications manufactured within the hospital;

(b) Procedures for admixture of parenteral products, including education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information. When the admixture of parenteral products is not accomplished under the direct supervision of a pharmacist, such preparation shall be limited to a practitioner or registered nurse;

(c) Manufacture and compounding of drugs;

(d) Procedures for establishment of specifications for procurement of all pharmaceutical materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the hospital;

(e) Procedures for participation in the development and revisions of a hospital formulary system;

(f) Procedures for filling and labeling all stock containers from which drugs are to be administered;

(g) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, as well as current antidote information, telephone numbers of poison control center(s) and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the hospital;

(h) Records of all transactions of the hospital relating to pharmaceutical services as may be required by state or federal law, and maintenance of accurate control over and accountability for all pharmaceutical materials. The procedures shall include the keeping of accurate and complete records of the receipt, withdrawal from stock and use or other disposal of all legend drugs stored in the drug room and all other locations in the hospital;

(i) Participation in those aspects of the hospital's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(j) Meeting all inspection and other requirements of the pharmacy and drug laws of this state and rules thereunder.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 3-1979(Temp), f. & ef. 10-31-79; 1PB 2-1980, f. & ef. 4-3-80

Pharmacists Serving Long Term Care Facilities and Community Based Care Facilities

855-041-0145
Definitions

As used in OAR 855-041-0145 through 855-041-0164:

(1)(a) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(b) For the purposes of Schedule II prescriptions in 21 CFR 1306.11–1306.13, the DEA definition of "long term care facility" as defined in 21 CFR 1300.01(25) includes "community based care facilities."

(2) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.

(3) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:

(a) Develop and maintain policies and procedures for pharmaceutical services;

(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:

(A) Receipt and interpretation of physician's orders;

(B) Ordering and receiving of medications;

(C) Handling of emergency drugs and supplies;

(D) Labeling of all drugs;

(E) Selection of drug delivery systems;

(F) Development of systems to provide timely delivery of drugs and supplies;

(G) Monitoring of drug storage conditions and expiration dates;

(H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;

(I) Establishing and monitoring of appropriate record keeping;

(J) Accountability of controlled substances;

(K) Return, release, and/or destruction of discontinued or outdated drugs; and

(L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.

(c) Provide training and in-service education to facility staff;

(d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:

(A) Over-utilization or underutilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug, drug dosage or duration of drug treatment;

(F) Drug-allergy interaction;

(G) Clinical abuse/misuse;

(H) Untreated indication;

(I) Monitoring and assessing of drug therapy outcomes.

(e) Communicate effectively with residents' physicians and facility staff; and

(f) Participate in resident care planning.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.0305
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

855-041-0160
Drug Distribution and Control

(1) Pharmacies or pharmacists that supply emergency drug kits to and/or accept returned medications from long term care facilities or community based care facilities must:

(a) Assist in the establishment and supervision of:

(A) The policies and procedures for the safe storage, distribution, administration, and disposition of drugs;

(B) The maintenance of controlled drug accountability records; and

(C) The policies and procedures for professional advice/medication counseling of patients and/or their care givers.

(b) Have some pharmacists visit and provide consultant services on a regular basis;

(c) Have some pharmacists perform the quality assurance activities defined in OAR 855-041-0132; and

(d) Supervise the implementation of the policies and procedures involving the security, storage, stocking, labeling, and notification of use of emergency drugs kits and supplemental drug supplies.

(2) Arrangements can be made in advance by a provider pharmacy with a long term care facility or a community based care facility to:

(a) Provide emergency drug kits to those facilities permitted by their license to have them; and

(b) Allow only a designated licensed nurse present in the facility access to the emergency drug kit or the on-site pharmacy pursuant to OAR 855-041-0120(3).

(3) An emergency drug kit consists of those drugs that may be required and are authorized by a practitioner to meet the immediate therapeutic needs of patients, when medication is not readily available directly from a pharmacy.

(4) The emergency drug kit inventory is the property of the provider pharmacy, and the provider pharmacy consultant is responsible for developing the policy and procedures for storing and stocking the emergency drug kit.

(5) Medication(s) can only be removed from the emergency drug kit or the on-site pharmacy by a designated licensed nurse pursuant to a practitioner's order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; PB 1-1990, f. & cert. ef. 1-23-90; PB 8-1990, f. & cert. ef. 12-5-90; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

855-041-0162
Labeling and Distribution

(1) Except as provided in subsection (2) of this section, all drugs dispensed for individual patients must be labeled as required by OAR 855-041-0065(6), or administered by health care professionals from a unit dose system as defined in OAR 855-041-0130(8).

(2) Pharmacies that provide long term care facilities or community based care facilities with pharmaceuticals can supply, on the order of a practitioner, and consistent with the policy and procedures of the pharmacy or pharmacist providing consultant services:

(a) Injectables for immunization and screening;

(b) Irrigation solutions; and

(c) Bulk manufacturer's container(s) of topical scabicides and pediculicides.

(3) Institutional pharmacies that dispense medications to patients in long term care facilities and community based care facilities must maintain for three years the records required by OAR 855-041-0065(4), and comply with the patient counseling requirements of OAR 855-041-0100(1).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

855-041-0164
Pharmaceutical Care in Community Based Care Facilities

When a pharmacist provides pharmaceutical care to patients in a Community Based Care facility under an arrangement with the facility, the pharmacist may provide the following services:

(1) Assist facilities in establishing the appropriate policies and procedures for distribution, storage, documentation and disposal of drugs;

(2) Assist facilities in establishing and maintaining proper record keeping related to medication administration;

(3) Visit the facility on a regularly scheduled basis;

(4) Supervise the distribution and storage of drugs;

(5) Assist in providing appropriate training, in-service education, and clinical support to facility staff; and

(6) Communicate with physicians and other practitioners as needed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

855-041-0165
Emergency Drug Supply in Home Health Care Agencies

Pharmacists serving home health care agencies may provide for an emergency supply of drugs to be made available to registered nurses to treat immediate therapeutic needs of their patients or clients during such time as the pharmacy services are not available. Arrangements shall be made in advance by the provider pharmacist for provision of the emergency drug supply:

(1) Emergency drugs defined. Emergency drugs are those non-controlled substances which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in a timely manner;

(2) Portable Container. Subject to all provisions of this section, a licensed pharmacy may furnish to a home health agency licensed by the State an emergency drug supply in a portable container for emergency in home treatment or adjustment of drug therapy by the home health agency nurse;

(3) Drugs included. The pharmacist(s) and the practitioner(s) who represent the agency shall jointly determine and review annually a list of items and quantities to be included in the emergency supply. Drugs shall only be available therein, in amounts sufficient for immediate therapeutic requirements. The selected list shall include only drugs to treat the following specific conditions:

(a) Allergic reactions;

(b) Diabetic emergencies;

(c) Severe nausea and vomiting;

(d) Pulmonary congestion or congestive heart failure;

(e) Local or topical anesthetics for catheter and needle placement;

(f) Hydration due to hypovolemia or shock;

(g) Routine catheter maintenance; and

(h) Narcotic analgesic overdose.

(4) Security. The emergency drug supply shall be stored in a manner to prevent loss of drugs, and available only to authorized licensed personnel. It may be kept in a room adjacent to the locked pharmacy, or in a secure area in the Home Health/Home I.V. nursing office;

(5) Storage. The emergency drug supply shall be stored in areas suitable to prevent unauthorized access and to insure a proper environment for preservation of the drugs as required in official compendia;

(6) Labeling-Exterior. The exterior of the emergency drug supply shall be labeled to clearly indicate it as an emergency supply. Labeling shall also include the expiration date of the drug supply. A complete listing of the contents of the supply shall be readily available;

(7) Labeling-Interior. All drugs contained in the emergency medication supply shall in the manu facturer's container or be labeled in accordance with OAR 855-041-0056;

(8) Drugs added to parenteral solutions. Whenever any drug is added to a parenteral solution, whether within or outside the direct personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of person so adding. This excludes any single dose medication prepared and totally administered immediately;

(9) Removal of drugs. Emergency drugs shall be removed for administration only by authorized licensed personnel pursuant to a prescriber's order. A copy of this order shall be forwarded to the provider pharmacist within 72 hours to be reviewed and filed in the pharmacy. Verification of this review shall be a hand written initial of the reviewing pharmacist on that copy of the order;

(10) Expiration Date. The expiration date of the emergency drug supply shall indicate the month and year, and shall be the earliest expiration date of any drug in the supply. The provider pharmacist shall examine the supply and replace drugs prior to their expiration.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.225
Hist. PB 1-1996, f. & cert. ef. 4-5-96; Renumbered from 855-041-0183; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

Correctional Facilities

855-041-0170
Purpose and Scope

A correctional facility is defined as an institutional drug outlet and as such is subject to the rules of the State Board of Pharmacy. Drug dispensing in a correctional facility shall be from a pharmacy or from a drug room. The facility shall have a pharmacist who acts as a consultant to the institution, develops policies and procedures on drug distribution, procurement and management, monitors for compliance, performs drug utilization reviews, and may delegate registered nurses to withdraw drugs for administration to patient/inmates.

Stat. Auth. : ORS 689.205
Stats. Implemented: ORS 689.005, 689.155 & 689.605
Hist. PB 1-1996, f. & cert. ef. 4-5-96

855-041-0173
Definitions

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner or the authorized agent thereof; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Bulk Drug Container" means a bottle or package of medication, other than unit dose, labeled by a manufacturer or pharmacist.

(3) "Container" is the device that holds the medication and that is or may be in direct contact with the medication.

(4) "Correctional Facility" means any prison, jail, or detention facility for the confinement of juveniles or adults.

(5) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to the lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(6) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.

(7) "Institutional Drug Outlet" means hospitals and inpatient care facilities where medications are dispensed to another health care professional for administration to patients served by the hospitals or facilities.

(8) "Medication card" means a medication container, labeled as required in OAR 855-041-0177(4), which provides multiple doses of a single medication with each dose contained in a separate, tamper-evident, sealed compartment.

(9) "Practitioner" means a person licensed and operating within the scope of such license to prescribe and dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

(a) In this state; or

(b) In another state or territory of the United States not residing in Oregon and registered under the Federal Controlled Substances Act.

(10) "Unit dose" means a sealed, single-unit container so designed that the contents are administered to the patient as a single dose, direct from the container and which bears a separate label showing the name and strength of the medication, the name of the manufacturer or distributor, an identifying lot number and, if applicable, the expiration date of the medication.

(11) "Unit Dose Dispensing System" means a system which utilizes unit dose as its principle means of distributing drugs within a correctional facility.

Stat. Auth. : ORS 689.205
Stats. Implemented: ORS 689.005 & 689.155
Hist. PB 1-1996, f. & cert. ef. 4-5-96

855-041-0175
Duties of the Pharmacist

(1) May delegate to a registered nurse the authority to withdraw prescription drugs from a unit dose system or from a manufacturer's or pharmacist's labeled container for administration to persons confined in the facility;

(2) Develop written policies and procedures with the practitioner representing the facility regarding medication management;

(3) Monitor the facility's compliance with policies and procedures regarding medication management;

(4) Perform drug utilization review including timely, routine prospective review of specific individual therapies as well as retrospective drug regimen reviews, and drug use review and evaluation.

Stat. Auth. : ORS 689.205
Stats. Implemented: ORS 689.605 & 689.155
Hist. PB 1-1996, f. & cert. ef. 4-5-96

855-041-0177
Drug Delivery and Control

(1) Policies and Procedures: The pharmacist and the practitioner representing the facility shall be responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures shall be reviewed and updated annually by the pharmacist and the practitioner, maintained in the facility; and be made available to the Board for inspection. The facility shall submit to the Board for approval, the name of any employee pharmacist or a written agreement between the pharmacist and the facility regarding drug policies and procedures. The facility shall notify the Board of any change of pharmacist within 15 days of the change.

(2) Dispensing: Prescription drugs shall be dispensed by a pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system.

(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:

(a) A unit dose dispensing system shall:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed and returned to the pharmacy;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the pharmacist to verify the prescriber's original order;

(v) Provide a means for the pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient; and

(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.

(b) Each correctional facility utilizing a unit dose dispensing system shall establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies shall be available in the pharmacy for inspection by the Board:

(A) Proper utilization of the unit dose system requires that, in as far as is practicable, all medications be in unit dose packaging when dispensed.

(B) Controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with OAR 855-041-0177(4).

(c) The pharmacist shall certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication shall be stored in a locked area or locked cart.

(4) Labeling: Prescription drugs dispensed in individual containers or medication cards shall be labeled with the following information:

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the pharmacist of the patient's record, the pharmacist shall initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent pharmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it shall include information that a reasonable and prudent pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Patient counseling shall be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third party delivery, counseling shall be in writing and by free access to the pharmacist by phone.

(d) Subsections (a) and (b) of this section shall not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a pharmacist is not required to provide oral counseling when a patient refuses the pharmacist's attempt to counsel, or when the pharmacist, on a case by case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.

(f) Board rules for patient counseling must be observed for patient/inmates who self administer or who are given prescription drugs when they are released from the correctional facility.

(6) Administration: Drugs shall be administered to inmate/patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined in Nursing Board administrative rule 851-047-0020. Drugs selected by registered nurses from manufacturer's or pharmacist's bulk drug containers shall not be administered by unlicensed persons, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

Stat. Auth. : ORS 689.205
Stats. Implemented: ORS 689
Hist. PB 1-1996, f. & cert. ef. 4-5-96; Administrative correction 11-3-99; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02

Technicians

855-041-0300
Out-of State Pharmacies

(1) Every out-of-state pharmacy that delivers prescription drugs or devices to a resident in this state shall be registered with the Oregon Board of Pharmacy.

(2) To qualify for registration under these rules, every out-of-state pharmacy shall be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(3) Every out-of-state pharmacy shall designate a pharmacist-in-charge, who shall be responsible for all prescription drugs and devices delivered to residents in Oregon. To qualify for this designation, the person must hold a license to practice pharmacy in the state of residence of the out-of-state pharmacy and in Oregon, and be in good standing with both licensing boards.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.225
Hist.: PB 1-1994, f. & cert. ef. 2-2-94; BP 2-2008, f. & cert. ef. 2-20-08

Retail Drug Outlet for Home Dialysis Supplies

855-041-0350
Purpose and Scope

A Retail Drug Outlet for Home Dialysis supplies may provide dialysis solutions under the general supervision and direction of a pharmacist with special training in renal disease and dialysis to end stage renal disease (ESRD) patients who have chosen the option of home dialysis therapy and who have been appropriately trained.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00

855-041-0355
Definitions

"Dialysis solutions" means peritoneal dialysis solutions, dialysate solutions, and legend devices including hardware, bloodlines and dialysis tubing and connectors.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00

855-041-0360
Drug Delivery and Control

(1) An Oregon licensed pharmacist must be designated as the pharmacist-in-charge who will provide direction and supervision of the operation and staff.

(2) Deliveries of supplies must be made only pursuant to a current prescription order from an authorized prescriber. The prescription order must be maintained on file at the outlet. Supplies will be limited to dialysis solutions as defined in OAR 855-041-0355. No other legend medication ordered for the patient may be provided by the outlet.

(3) All patient records must be maintained in a secure area with a locking door. Access to the patient records area is allowed only when a pharmacist is present except in the event of an emergency. In the event of an emergency, any entry by individuals other than the pharmacist must be documented. In the absence of a pharmacist, the door to the patient records area must remain locked at all times.

(4) Copies of all prescriptions must be reviewed by the pharmacist and a complete set of prescription records for all patients serviced by the outlet must be maintained in the patient records area for a minimum of three years.

(5) A minimum of two current reference books that are specific and relevant to dialysis therapy must be maintained in the outlet to assist in the appropriate delivery of care to patients. Other reference material and equipment must be maintained to be consistent with the scope of services provided by the outlet.

(6) A current copy of Oregon Revised Statutes, Chapter 689, a current copy of Oregon Administrative Rules, chapter 855, and a minimum of three years of the Oregon Board of Pharmacy quarterly newsletters must be maintained in a loose leaf binder or other readily retrievable means.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00

855-041-0365
Duties of the Pharmacist

(1) The pharmacist-in-charge must review, at least weekly, the drug outlet operation and perform, at least monthly, quality assurance audits that include the review of prescription orders prior to delivery for accuracy and completeness, and the review of the assembled order with the prescription order prior to delivery for accuracy and completeness.

(2) The pharmacist-in-charge is responsible for the following on an ongoing basis:

(a) Ensure compliance of dialysis distribution operation to all applicable federal and state pharmacy laws and rules;

(b) Ensure valid prescriptions are received for all patient orders by performing periodic assessments of prescription files;

(c) Perform periodic assessments of distribution processes and procedures to ensure quality and compliance;

(d) Provide pharmaceutical care by reviewing all patient profiles and performing drug therapy assessments on those identified as abnormal;

(e) Provide pharmaceutical care by responding on a toll free telephone access to questions received from any patient or health care provider;

(f) Maintain, update and train personnel on policies and procedures specific to home dialysis patient deliveries and pharmacy requirements;

(g) Prepare educational materials for staff members of dialysis clinics as requested;

(h) Prepare and maintain on file monthly reports of activities performed;

(i) Ensure security of the patient record area; and

(j) Maintain a policy and procedure manual for the Drug Outlet operation that must include written protocols for the product delivery system, methods for supervising deliveries to patients, and a quality assurance program with which to monitor the qualifications, training and performance of personnel.

(3) The pharmacist-in-charge must perform an annual inspection of the outlet on a form provided by the Board, and must provide a copy of this inspection to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00

Remote Dispensing

855-041-0600
Definitions

(1) "Automated Pharmacy System" (APS) means a mechanical system that performs operations or activities, including but not limited to, those related to the storage, packaging, dispensing, or distribution of medications, but not including compounding or administration, and that collects, controls, and maintains all transaction information.

(2) "Remote Dispensing Facility" (RDF) means a facility where drugs are prepared for administration and where requisite pharmacist supervision is provided remotely as approved by the Board.

(3) "Remote Dispensing Machine" (RDM) means a component of an Automated Pharmacy System that contains prepackaged drugs for dispensing.

(4) "Responsible Pharmacy" means the licensed pharmacy that is responsible for the APS, and RDM.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; BP 9-2010(Temp), f. & cert. ef. 7-9-10 thru 12-24-10

855-041-0610
Duties and Responsibilities of the Pharmacist-in-Charge.

Each RDM must be under the supervision of the Pharmacist-in-Charge of the Responsible Pharmacy. The Pharmacist-in-Charge must:

(1) Develop written policies and procedures prior to installation of the RDM that:

(a) Ensure safety, accuracy, security, and patient confidentiality;

(b) Define access to the RDM and to medications contained within or associated with the RDM, including but not limited to policies that assign, discontinue, or change access to the RDM and medications.

(c) Ensure that access to the medications complies with state and federal laws and regulations.

(2) Obtain written approval by the Board prior to installing any RDM.

(3) Train all personnel who will access the APS (including the RDM) before being allowed access to the APS. Training must ensure the competence and ability of all personnel who operate any component of the APS. Documentation of original training and continuing education must be kept both in the pharmacy and at the site of the RDM, and readily available for inspection by the Board.

(4) Ensure that the RDM is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record-keeping and security safeguards.

(5) Implement an ongoing quality assurance program that monitors performance of the APS, including the RDM, and the personnel who access it.

(6) Notify the Board within 15 days of removal or closure of the RDM and the disposition of drugs contained in the RDM before it was removed or closed.

(7) Ensure that the RDM is stocked accurately and in accordance with established, written policies and procedures. A pharmacist must check the accuracy of the product supplied for stocking the machine.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.205
Hist.: BP 2-2005, f. 2-14-05, cert. ef. 3-1-05

855-041-0620
Drug Delivery and Control

(1) Each RDM must be registered with the Board, under the control of and connected via computer with a Responsible Pharmacy, but not located in a pharmacy. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws and regulations.

(2) The following must be conspicuously displayed at the site of the RDM:

(a) RDM license;

(b) DEA registration if required;

(c) A certified copy of the Responsible Pharmacy license; and

(d) A certified copy of the Pharmacist-In-Charge license.

(3) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained in the pharmacy for review by the board. Such documentation must include, but is not limited to:

(a) Location of RDM(s);

(b) Manufacturer's name and model for each RDM;

(c) Description of how the RDM is used;

(d) Quality assurance procedures to determine continued appropriate use of the automated device; and

(e) Policies and procedures for training of appropriate personnel, system operation, safety, security, accuracy, patient confidentiality, oral counseling by a pharmacist or pharmacist-intern, access, and malfunction.

(4) Policies and procedures addressing the operation of the RDM must be maintained in the pharmacy responsible for the APS and at the location at which the RDM has been installed.

(5) All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the pharmacy for a minimum of three years and must be readily available to the Board. Such records shall include:

(a) Identity of RDM accessed;

(b) Identification of the individual accessing the RDM;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form, and quantity of the drug accessed;

(f) Name of the patient for whom the drug was ordered;

(g) Name of the prescribing practitioner;

(h) Such additional information as the pharmacist-in-charge may deem necessary; and

(6) Only an Oregon registered technician or an Oregon licensed pharmacist may have access to the RDM.

(7) Only an Oregon registered technician or an Oregon licensed pharmacist may stock medications in the RDM.

(8) All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws and regulations, including OAR 855-041-0065(6)(a)–(k).

(9) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(10) Oral counseling, as required by OAR 855-041-0100, shall be provided by the pharmacist at the time of dispensing by a two-way audio and video hookup with the Responsible Pharmacy.

(11) The Automated Pharmacy Systems shall provide a mechanism for securing and accounting for wasted, discarded or unused medications in accordance with existing state and federal laws and regulations.

(12) The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist-In-Charge.

(13) A Responsible Pharmacy located outside of Oregon that operates a RDM in Oregon must be currently licensed and in good standing in Oregon. The Pharmacist-In-Charge must also be currently licensed and in good-standing both in Oregon and in the state in which the Responsible Pharmacy is located.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.205
Hist.: BP 2-2005, f. 2-14-05, cert. ef. 3-1-05

855-041-0640
Remote Dispensing Facility (RDF)

(1) A pharmacy physically located in Oregon may make written application to operate an RDF.

(2) At its discretion, the Board may approve an application for registration as an RDF, which includes the following:

(a) An operation plan;

(b) Policies and Procedures;

(c) A training plan;

(d) A quality assurance plan for ensuring that there is a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems; and

(e) The fee specified in OAR 855-110-0007(14).

(3) Notwithstanding the definition of "supervision by a pharmacist" in OAR 855-006-0005, supervision in an RDF may be accomplished by a pharmacist via an audio-visual technology from the applying pharmacy.

(4) Notwithstanding rules in this division and in division 019, a Certified Pharmacy Technician who works in an RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 9-2010(Temp), f. & cert. ef. 7-9-10 thru 12-24-10

Expedited Partner Therapy

855-041-4000
Purpose

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

855-041-4005
Procedures

(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule shall govern.

(3) An EPT prescription may only be dispensed for a drug that has been determined by the Department of Human Services (DHS) to be appropriately used for EPT.

Prescription

(4) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a hand written or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the pharmacist must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.

Labeling

(6) The pharmacist must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(7) The pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

Hospitals with Pharmacies

855-041-6050
Definitions

(1) In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(a) "Automated Distribution Cabinet" (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;

(b) "Drug" means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(c) "Central pharmacy" means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;

(d) "Chief Pharmacy Officer" (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(e) "Drug profile" means a complete and comprehensive summary of a patient's current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;

(f) "Licensed Independent Practitioner" (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;

(g) "Out-patient" means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;

(h) "Remote storage area" means a patient care area which is part of the hospital that is under the supervision and control of the hospital's central pharmacy but is not located in the same building as the central pharmacy;

(i) "Secondary drug storage area" means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;

(j) "Unit-dose" means a quantity of a drug designed to be administered to a patient, such as:

(A) An oral solid individually packaged or re-packaged;

(B) An oral liquid drawn up in a labeled oral syringe;

(C) An injectable product; or

(D) A pre-mixed IV product.

(2) Not withstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6100
Registration

(1) Each central pharmacy must be registered with the Board. In a hospital with multiple central pharmacies, each pharmacy location must be registered with the Board.

(2) A secondary drug storage area within the hospital or in a structure physically attached to the hospital does not require a separate registration.

(3) A registered pharmacy in a hospital may use additional locations within the hospital, supervised by a pharmacist, without acquiring separate registrations for each additional location.

(4) A secondary drug storage area in a separate location must be registered as a drug room and must follow all rules that apply to secondary storage areas in the hospital.

(5) A residential healthcare facility that is licensed by DHS and that has a central pharmacy must register the pharmacy with the Board.

(6) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.305
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6150
General Pharmacy Requirements

(1) Each hospital pharmacy must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC).

(2) A hospital that has more than one pharmacy must designate an Oregon licensed pharmacist as CPO or an equivalent position who has responsibility for directing pharmacy services in the hospital. The CPO may also be the PIC of one of the pharmacies.

(3) A hospital pharmacy may only be operated when under the direct supervision of an Oregon licensed pharmacist. The pharmacist shall be responsible for all areas of the hospital where drugs are stored, including remote storage areas

(4) The pharmacy must be operated at least part-time, five days a week.

(5) The hospital pharmacy must have adequate space so that drugs can be prepared in sanitary, well-lit, enclosed places. Space and equipment must be adequate for the pharmaceutical services provided including compounding, distributing, and storage of drugs and parenteral preparations.

(6) As a minimum, the pharmacy must have the following:

(a) Equipment listed in OAR 855-041-0040, except that a pharmacy that is only registered as an institutional drug outlet does not need to have an Official Poison and Exempt Narcotic Register;

(b) A drug formulary approved by the appropriate hospital committee;

(c) Pharmacy policy and procedures.

(7) All areas occupied by a hospital pharmacy must be secured to prevent access by unauthorized personnel.

(a) Whenever any area of a hospital pharmacy is not under direct supervision of a pharmacist, the area must be secured;

(b) The CPO shall designate in writing, by title and specific area, those persons who may have access to specific areas within the pharmacy;

(c) Unless otherwise permitted by these rules, a non-pharmacist may not have access to the pharmacy unless a pharmacist is on duty and present in the hospital.

(8) A residential healthcare facility that has a central pharmacy must comply with these rules.

(9) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Drug Distribution and Control

855-041-6200
Chief Pharmacy Officer and Pharmacist in Charge

(1) The CPO must specify the respective responsibilities of the CPO and the PIC if separate individuals hold these positions.

(2) In addition to the duties listed in this rule, the PIC has the responsibilities listed in OAR 855-019-0300.

(3) The CPO must establish policies and procedures that include:

(a) Procedures for general distribution of drugs throughout the hospital;

(b) A procedure for review and revision of the policies and procedures not less than every three years;

(c) Procedures for the supervision of pharmacy services including storage, distribution, control and accountability for drugs including controlled drugs;

(d) Procedures to ensure that all areas of the hospital where drugs are stored are inspected not less than every two months to verify proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the emergency drug supplies;

(e) Policies and procedures that govern the preparation, verification and sterilization of parenteral drugs compounded within the hospital. Procedures must comply with OARs 855-045-0200 through 855-045-0270 and these rules;

(f) Procedures for administration of drugs, including self-administration;

(g) Procedures for labeling drugs;

(h) Policies and procedures that govern the filling and labeling of containers from which drugs are to be administered;

(i) Procedures for a Quality Assurance program to ensure that there is a planned, ongoing and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services, and for identifying and resolving problems. Such monitoring and evaluation must be accomplished through ongoing collection of information and periodic assessment of the collected information;

(j) Emergency drug distribution;

(k) Procedures for procurement of all drugs subject to approval of the appropriate committee of the hospital;

(l) Procedures to ensure that discontinued, outdated, adulterated or misbranded drugs are returned to the pharmacy for proper disposition, or that the PIC makes proper disposition or disposal of such drugs at the storage site;

(m) A recall procedure that can be quickly activated to assure the CPO and pharmacy staff, and the medical staff that all drugs included in the recall have been returned to the pharmacy for proper disposition;

(n) Policies and procedures for the use of investigational drugs;

(o) Procedures to be followed in the absence of the pharmacist.

(4) The CPO must:

(a) Participate in the development and revisions of a hospital formulary;

(b) Maintain an emergency and disaster plan for pharmacy services, and participate in the facility's emergency and disaster plan;

(c) Ensure that records of all transactions of the hospital pharmacy that are required by state and federal laws and regulations are maintained, and maintain accurate control and accountability for all pharmaceutical materials;

(d) Participate in the hospital's Quality Assurance program related to drugs;

(e) Comply with all inspection and other requirements of the pharmacy in accordance with all applicable state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6220
Records

(1) Unless specified otherwise, all records and documentation required by these rules, OAR 855-041-6000 through 855-041-6999 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

(a) Patient profiles and drug administration records;

(b) Reports of suspected adverse drug reactions;

(c) Inspections of drug storage areas;

(d) Annual controlled substance inventories;

(e) Controlled drug accountability reports;

(f) Collaborative Drug Therapy agreements;

(g) Current hospital drug formulary;

(h) Any other records and reports required by state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.508
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6240
Drug Administration

(1) In a hospital, a drug may only be administered upon an order initiated by:

(a) A member of the medical staff who has been granted clinical privileges;

(b) An authorized member of the house staff; or

(c) An authorized licensed practitioner.

(2) Each administration of a drug must be in accordance with policies and procedures approved by the appropriate committee of the hospital, must comply with all applicable laws, rules and regulations, and must follow usual and customary standards of good medical practice.

(3) Self-administration. A patient may only be permitted to self-administer a drug when specifically authorized by the treating or ordering practitioner, and when the patient has been educated and trained in the proper self-administration of the drug.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6250
Patient's Own Drugs and Other Drugs from Outside Sources

When a patient or a patient's agent brings a drug into the hospital, the drug may only be administered to the patient if:

(1) The practitioner or pharmacist has identified it and it is in a pharmacy labeled container; and

(2) Any administration is pursuant to a practitioner's order; or

(3) In the pharmacist's professional judgment, withholding the drug would be detrimental to the patient's health. In such a case, the pharmacist may authorize administration of the drug pursuant to a practitioner's order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6260
Investigational Drugs

(1) All in-patient investigational drugs must be stored in the pharmacy and may only be distributed from the pharmacy when properly labeled.

(2) Information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs must be available in the pharmacy.

(3) Investigational drugs may only be ordered by a designated physician-investigator or their authorized clinician, subject to the prior approval of the appropriate hospital committee.

(4) Each order must include the appropriate protocol number.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6270
Labeling

(1) Each pharmacy record keeping system must identify and document the pharmacist who verifies the drug.

(2) Each pre-packed drug, including a unit-dosed drug, prepared by the pharmacy and intended for use within the facility shall be in an appropriate container with a label that contains:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is to be sent with the patient upon discharge must be labeled in accordance with ORS 689.505(5) and other rules in this Division. Drug counseling information must be provided to the patient or patient's agent.

(5) A label for an outpatient prescription must comply with ORS 689.505(5) and other rules in this Division.

(6) New bar coding or electronic label: When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(7) Whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that contains

(a) The name, quantity and concentration of the drug added and the primary solution;

(b) The date and time of addition;

(c) The expiration date;

(d) The scheduled time for administration;

(e) The infusion rate, when applicable;

(f) The name or initials of person performing admixture;

(g) The identification of the pharmacy where the admixture was performed; and

(h) The name or initials of the verifying pharmacist.

(8) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.505
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Absence of a Pharmacist

855-041-6300
Untitled

The CPO must make appropriate arrangements for provision of drugs to the medical staff and other authorized personnel by use of a night cabinet or by access to the pharmacy, or both, for situations when hospital pharmacy services are not available.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.605
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6305
Night Cabinet

(1) If a night cabinet is used, the following procedures must be followed:

(a) The cabinet or other enclosure located outside the pharmacy must be secure from unauthorized access;

(b) Only one authorized registered nurse on a shift may have access to the night cabinet and may remove drugs. Such nurse must be designated in writing by the appropriate committee of the hospital and prior to being given access to the night cabinet, must receive

appropriate training in the proper procedures for access, removal of drugs, and recordkeeping;

(c) The PIC or designee must give this training, and must require, at a minimum, the following procedures:

(A) A drug may only be removed from the night cabinet on a practitioner's written order or a verbal order that has been reduced to writing;

(B) A copy of the practitioner's order must be left in the night cabinet for the pharmacist to verify for accuracy. Both the nurse supervisor and the verifying pharmacist must initial the order.

(2) In conjunction with the appropriate hospital committee, the CPO must develop an inventory of those drugs to be included in each cabinet and establish procedures to ensure that:

(a) Drugs are available and labeled as required by these rules;

(b) Only prepackaged drugs are placed in the cabinet;

(c) Quantities do not exceed those reasonable for immediate therapeutic requirements;

(d) Whenever a cabinet has been accessed, a written record is kept of the drug order and certification of the drug use;

(e) Controlled substances are kept securely and are accounted for using a reconciled perpetual inventory;

(f) An audit of controlled substances in the cabinet is conducted at least once per month. If a tamper-evident seal system is not used, a quality assurance program must be in place to identify any diversion.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.605
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6310
After Hours Access to Pharmacy

When a drug required to treat the immediate needs of a patient is not available from floor-stock or a night cabinet, it may be obtained from the pharmacy in accordance with the following procedures:

(1) Only one registered nurse supervisor on a shift may have access to the pharmacy and may remove drugs. The nurse supervisor must be designated in writing by the appropriate hospital committee and prior to being permitted to obtain access to the pharmacy, must receive appropriate training in the proper procedures for access, removal of drugs, and recordkeeping;

(2) The PIC or designee must give such education and training, and must require, at a minimum, the following procedures:

(a) A drug may only be removed from the pharmacy on a practitioner's order that has been posted to the patient's medical record;

(b) A copy of the practitioner's order must be left either with the container from which the drug was removed or with an identical unit-dose, and must be placed conspicuously for a pharmacist to verify for accuracy;

(c) A record of each drug removed from the pharmacy by the nurse supervisor must include:

(A) Name and hospital location of the patient;

(B) Name and strength of drug distributed;

(C) Units used;

(D) Date and time of distribution;

(E) Initials of the nurse supervisor distributing the drug;

(F) Date and initials of the pharmacist who confirmed the accuracy of the transaction.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.605
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Outpatient Drug Distribution

855-041-6400
Emergency Dispensing by a Nurse

A hospital may provide for the emergency dispensing of a drug to an outpatient who is under the care of a practitioner who is a member of the hospital medical staff, when there is a legitimate medical need as described in hospital policies and procedures.

(1) A designated registered nurse may dispense a drug to an outpatient subject to the following:

(a) There is a prescription from a practitioner authorized to prescribe the drug or a verbal order that the nurse has reduced to writing. A practitioner who issues a verbal order or prescription must send a written prescription to the hospital pharmacy within seven days;

(b) The drug is in a manufacturer's bulk unit-of-use, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with;

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug;

(E) Name, address and phone number of the hospital pharmacy.

(c) The following information must be added to the drug container by the nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number;

(E) Name of prescribing practitioner;

(F) Initials of the dispensing nurse or practitioner.

(d) The patient must be given instructions on the use and precautions for taking the drug;

(e) A prescription must be completed by the practitioner or nurse. This prescription must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Name and strength of drug distributed;

(D) Units issued;

(E) Name of practitioner and initials of dispensing nurse;

(F) Instructions given to the patient.

(f) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient.

(2) The patient may not be given more than an emergency supply, as that is defined in the hospital policy and procedures.

(3) The pharmacist must verify, document and date the original prescription.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.505
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6410
Emergency Department Distribution

(1) A practitioner who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:

(a) There is an order from a practitioner authorized to prescribe the drug in the patient's medical record;

(b) The drug is in a manufacturer's bulk unit-of-use, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug;

(E) Name, address and phone number of the hospital pharmacy.

(c) The following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number as determined by policy and procedure;

(E) Name of prescribing practitioner;

(F) Initials of the dispensing nurse or practitioner.

(d) The patient must be given instructions on the use and precautions for taking the drug;

(e) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:

(A) Name of patient;
(B) Date of issuance;
(C) Drug name and strength distributed;
(D) Units issued;
(E) Name of practitioner;
(F) Initials of the dispensing nurse or practitioner; and
(G) Instructions given to the patient.

(f) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;

(g) The record must be reviewed and documented by a pharmacist for accuracy and completeness.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The pharmacy must determine the amount of each drug that constitutes an emergency supply. That amount may not exceed a four-day supply except for;

(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.505
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

In-Patient Drug Distribution

855-041-6420
Emergency Kit and Code Cart

An emergency kit consists of those drugs which may be required to meet the immediate therapeutic needs of in-patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

(1) An emergency kit may be placed in a code cart or as a stand-alone emergency kit.

(2) A pharmacist must verify and document the contents of each emergency kit.

(3) The CPO in cooperation with the appropriate hospital committee shall determine the list and quantity of drugs to be included in an emergency kit. The CPO must ensure that this list is reviewed annually.

(4) An emergency drug kit must use a tamper-evident system and be stored to prevent unauthorized access.

(5) All drugs in emergency kits and code carts must be labeled in accordance with OAR 855-041-6270.

(6) An emergency kit or code cart must be labeled to indicate that it is a drug supply for emergency use. A label must also contain the name, strength, quantity of all drugs in the kit or code cart and the expiration date of the kit. The label shall be affixed to or be available on the exterior of the code cart.

(7) The expiration date of an emergency kit or code cart must be the same as the earliest expiration date of any drug in the kit or cart. Prior to the expiration date, the pharmacist must replace expired drugs.

(8) Only an authorized person may remove a drug from an emergency kit or code cart. Any removal must be pursuant to a valid order or approved protocol.

(9) The pharmacy must be notified when an emergency kit or code cart has been opened or has expired and the pharmacist must restock or replace the emergency kit within a reasonable time.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6500
Practitioner's Drug Order

(1) An order for a drug for an in-patient must be transmitted to the pharmacy using a system that produces a direct or an electronic copy.

(2) A pharmacist must review the drug order before the initial dose is dispensed, and must document the review and DUR except:

(a) When a drug is dispensed under OAR 855-041-6310;
(b) In an emergency;
(c) When pharmacy services are not available; or
(d) When a LIP is present.

(3) An order for a drug must contain:

(a) The patient's name and location;
(b) The drug name and strength;
(c) Route of administration;
(d) Directions for use;
(e) The date and time; and
(f) The practitioner's written or electronic signature, or the signature of the practitioner's agent.

(4) The hospital must follow the following procedures for verbal drug orders:

(a) A verbal drug order should be used infrequently;

(b) A verbal drug order of an authorized individual may be accepted and transcribed only by a qualified person who has been identified by title or category in the hospital policies and procedures;

(c) A verbal order must be reduced to writing and read back to the prescribing practitioner to verify accuracy;

(d) A verbal order must be signed or initialed by the prescribing practitioner as soon as possible.

(5) A drug administered to a patient must be ordered by an authorized prescribing practitioner or otherwise allowed by these rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6510
In-patient Drug Profile

(1) Each pharmacist must ensure that a drug order for a patient requiring continuous drug therapy is entered into the patient's drug profile. The profile must contain:

(a) The patient's name, location and important clinical data such as age, height, weight, sex, chronic disease states, problem list and allergies;

(b) The drug name, strength, dosage form, route of administration and directions for administration;

(c) The drug therapy start and end date as applicable;

(d) The name or ID of the pharmacist responsible for entry or verification of the drug order.

(2) Prior to the drug being released for access by the nurse, a pharmacist must enter the drug order into a drug profile and perform a DUR except when:

(a) The drug is being dispensed from an after-hours cabinet in the absence of a pharmacist;

(b) The drug is from an emergency drug kit; or

(c) A system override is being used by a LIP or nurse to treat the emergency needs of a patient. Subject to a prescriber's order, a sufficient quantity to meet the emergency needs of the patient may be used until a pharmacist is available to review and confirm the drug order.

(3) The pharmacist must continue to monitor the appropriateness of the patient's drug utilization throughout the patient's stay in the hospital.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6520
Cart-Fill

(1) A unit-dose cart-fill system is a pharmacy controlled unit-of-use drug distribution system.

(a) A unit-dose cart-fill system must provide for separation of drugs by patient name and location, and must be designed to record in an individual patient's record:

(A) The drug, dose strength, and dosing regimen of those drugs dispensed by the pharmacy;

(B) The number of doses dispensed;

(C) The date of the original order, and the date the order is discontinued.

(b) The system must:

(A) Provide a means for the pharmacist to verify the prescriber's original order;

(B) Provide a means for the pharmacist to verify the accuracy of the selected drug before the dose is delivered for administration to the patient; and

(C) Provide a mechanism to identify controlled substances.

(c) The pharmacist must verify the prescriber's original order and the accuracy of the selected drug.

(2) Controlled substances may be included in the unit-dose system if the system complies with all applicable state and federal laws and regulations.

(3) Each drug must be in unit-dose packaging when dispensed except when this is impracticable.

(4) A drug not dispensed in unit-dose packaging must be labeled in accordance with other rules in this Division.

(5) A drug in a single container multiple-dose package such as an inhaler or a topical drug must be labeled with the patient's name and location within the facility.

(6) A pharmacy technician, certified pharmacy technician, intern or pharmacist may fill daily unit-dose drug supplies for a hospital inpatient or a nursing home patient.

(7) The pharmacist must verify the accuracy of a unit-dose package before the dose is delivered for administration to the patient.

(8) Each drug must be stored in a locked area or locked cart.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6530
Robotic Distribution Systems

(1) A robotic drug distribution system used in a central pharmacy must be in a secure area under the control of the PIC and must be connected with the system that contains the patient's drug profile.

(2) The pharmacy must maintain the following documentation for each system:

(a) Details of the equipment including manufacturer's name, model and serial number;

(b) A description of how the system is used;

(c) Policies and procedures that include:

(A) Quality assurance performed at least quarterly including a requirement that a pharmacist visually verifies the accuracy of the electronic or bar code labeling using an audit procedure that includes random sampling;

(B) Procedures for training personnel in safe system operation, security, accuracy, patient confidentiality, access and downtime procedures.

(3) All distribution records must be recorded electronically and retained for 3 years or as approved by the Board. Records must include:

(a) Identity of robotic drug distribution system accessed;

(b) Type of transaction;

(c) Date and time of transaction;

(d) Name, strength, dosage form, and quantity of the drug accessed;

(e) Identity of the patient for whom the drug was ordered;

(f) Any other information the PIC may deem necessary.

(4) Only a pharmacy technician, certified pharmacy technician, intern, pharmacist or a person designated by the PIC may have access to the system.

(5) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may stock drugs in the system.

(6) All drugs in the system must be packaged and labeled in accordance with state and federal laws and regulations.

(7) Controlled Substances:

(a) Controlled substances must be handled in accordance with all applicable state and federal laws and regulations;

(b) Schedule III, IV and V drugs may be stocked in a robotic drug distribution system provided there is adequate security to limit access to those personnel designated by the PIC;

(c) Schedule II drugs may not be stocked in any robotic drug distribution system.

(8) Drugs prepared by a robotic system must be packaged and separated by patient or as approved by hospital protocol, prior to distribution for administration.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.508
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6540
Automated Distribution Cabinets

(1) Each ADC must be under the control of the pharmacy. The PIC must establish policies and procedures to meet the requirements of all applicable state and federal laws and regulations.

(2) Policies and procedures addressing the operation of the ADC must be maintained in the pharmacy. They must include:

(a) Training of personnel granted access to the ADC;

(b) System operation, safety, security, access, accuracy and patient confidentiality;

(c) Cabinet replenishment procedures;

(d) Downtime procedures;

(e) A procedure for securing and accounting for any wasted, discarded or unused drug in accordance with existing state and federal laws and regulations.

(3) All events involving the contents of the ADC must be recorded and must include:

(a) Identity of ADC accessed;

(b) Identification of the individual accessing the ADC;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form and quantity of the drug accessed;

(f) Name of the patient or patient identifier for whom the drug was ordered;

(g) Such additional information as the PIC may deem necessary.

(4) Only a pharmacist, pharmacy technician, certified pharmacy technician, intern or other person designated by the PIC may have access to the ADC.

(5) Stocking drugs in an ADC:

(a) Only a pharmacy technician, certified pharmacy technician, intern, pharmacist or other licensed healthcare personnel designated by the PIC may stock drugs in the ADC;

(b) A pharmacist must visually or electronically verify the name, strength and accuracy of the drug to be released from the central pharmacy for restocking;

(c) When a barcode or other electronic system is used to confirm the accuracy of the replenishment of the stock in an ADC, the system must receive an initial quality assurance validation;

(d) When all drug doses for an individual storage unit or bin have been packaged in one container, a single barcode verification may be used;

(e) The PIC must monitor the accuracy of the replenishment of drugs with a quality assurance process that includes:

(A) Reconciling the ADC fill list with established unit specific drugs using the drug profile, ADC discrepancy and inventory reports; and

(B) Monitoring the accuracy of the restocking and withdrawal procedures used by all hospital staff approved for drug administration.

(f) The PIC may permit medical supplies and devices to be included in the ADC.

(6) All drugs stored in the ADC must be packaged and labeled in accordance with state and federal laws and regulations.

(7) A drug that has been removed from the ADC for any purpose may not be returned to the system unless:

(a) A pharmacist has examined the drug, the packaging, and the labeling and determined that reuse of the drug is appropriate; or

(b) It is a drug, such as a multi-dose vial, which has been exempted by the appropriate hospital committee.

(8) At the time of loading, unloading, inventorying, removing or accessing any controlled substance from the ADC, a blind count or confirmation of the correct count must be conducted. Any discrepancy must be reported immediately to the PIC or pharmacist on duty who is responsible for reconciliation of the unresolved discrepancy or proper reporting of the loss.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6550
Secondary and Remote Storage

(1) All drugs must be stored in designated areas to ensure proper sanitation, temperature, light, ventilation, moisture control, and security.

(2) Drugs may only be stored in nursing units when space is available for the storage, security, and preparation of drug doses. Such space must include:

(a) A locked drug cabinet or room that is equipped so that each patient's drugs are separated physically or electronically. Drugs may be stored in secured individual patient storage areas or individually labeled for each patient;

(b) A container or compartment that is permanently attached to a storage cart or the drug room in which controlled substances can be secured;

(c) Alcohol and other flammables must be stored in areas that meet local building code requirements for the storage of volatiles, and such other laws and regulations that apply.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Floor-stock and Non-Emergency Trays and Kits

855-041-6560
Floor-Stock

(1) A minimal quantity of drugs may be stocked in patient care areas to meet the immediate therapeutic needs of a patient where delay would interrupt the continuity of, or compromise the care of the patient.

(2) A hospital pharmacy must not use a floor-stock drug distribution system as its primary system of drug distribution except in departments staffed with a LIP such as the Emergency Room, Operating Rooms and Radiology.

(3) The CPO, in consultation with nursing staff, must prepare a list of drugs by identity and quantity for each area where such supplies are stocked. This list must be kept in the pharmacy.

(4) Floor-stock drug supplies must be stored in a secure area only accessible to pharmacy-authorized personnel.

(5) All drugs in floor-stock must be labeled in accordance with other rules in this Division.

(6) Drugs may only be removed from floor-stock by personnel authorized by the appropriate hospital committee. A drug may only be removed pursuant to a valid prescriber's order. Removal from stock must be recorded in accordance with policy and in the patient's medical record.

(7) The CPO may permit medical supplies and devices to be included in the floor-stock.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6570
Trays and Kits

(1) All drug trays and kits must be prepared by the pharmacy prior to release from the central pharmacy except that trays and kits may be prepared from floor-stock by an LIP who administers the drug or by authorized hospital staff in the case of emergency use if:

(a) The pharmacy and appropriate hospital departments jointly develop guidelines for the proper use, preparation, and security for the trays or kits; and

(b) The pharmacy has a quality assurance program for monitoring the proper use, preparation and security of the kits.

(2) A pharmacist must verify the accuracy and secure the contents of each tray or kit prepared in the pharmacy prior to release from the central pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Controlled Substances

855-041-6600
Controlled Drug Accountability

(1) The hospital must establish procedures and maintain records to account for all controlled substances and any other drugs designated by the appropriate hospital committee. Records must include:

(a) Name of drug;

(b) Dose ordered, dose dispensed, and dose administered;

(c) Identity of patient;

(d) Date and time of administration;

(e) Person administering the drug;

(f) Verification and documentation of any wasted drug including partial doses.

(2) The pharmacy must provide separately locked, securely affixed compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single-unit packaged drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(3) The pharmacy must obtain a delivery receipt for all controlled drugs supplied as floor-stock. This record must include the date, drug name and strength, quantity, hospital unit receiving drug and the signatures of the distributing pharmacist and the receiving nurse.

(4) A record must be kept of each administration of a controlled drug from floor-stock. The record must be returned to the pharmacy monthly and the PIC or designee must:

(a) Match returned records with delivery receipts to verify that all records are returned;

(b) Periodically audit administration records for completeness;

(c) Reconcile administration records with inventory and verify that sums carried from one record to the next are correctly recorded;

(d) Periodically verify that doses documented on administration records are reflected in the medical record; and

(e) Initial the returned record and file by date of issue.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165 & 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6610
Schedule II Drugs

(1) In addition to the requirements above, Schedule II record keeping must include:

(a) A perpetual inventory system for all Schedule II drugs received, stored and distributed by the pharmacy. The perpetual inventory must be reconciled with an actual inventory at least monthly and the results and any discrepancies must be noted;

(b) Schedule II drugs stored as floor-stock in patient-care areas must be controlled with a perpetual inventory system that includes an actual inventory count and reconciliation when the department or nursing unit is open. The CPO must develop policies and procedure to ensure a regular audit of the inventory;

(c) Quality assurance procedures for the random sample of perpetual inventory sheets including sign-out sheets or other dose-by-dose documentation, must be performed at least quarterly and must be used to determine the accuracy and effectiveness of Schedule II floor-stock drug control;

(d) All Schedule II drugs stored in the pharmacy must be kept in a locked area or secured storage system that tracks the identity of each person making entry into and out of the system whenever a pharmacist is not physically present in the department.

(2) Policies and Procedures must specify the conditions under which Schedule II controlled substances can be transferred into or removed from an ADC.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165 & 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6620
Electronic Safe Systems

(1) The pharmacy must maintain policies and procedures that address the operation of any electronic safe system. These policies must include:

(a) Training of personnel granted access to the electronic safe system;

(b) System operation, safety, security, access, accuracy and patient confidentiality;

(c) Downtime procedures.

(2) All events involving the contents of the electronic safe system must be recorded electronically. Such records must include:

(a) Identity of electronic safe system accessed;

(b) Identification of the individual accessing the electronic safe system;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form, and quantity of the drug accessed;

(f) Name of the patient for whom the drug was ordered when applicable;

(g) Any additional information that the CPO requires.

(3) Only a pharmacist, pharmacy technician, certified pharmacy technician or intern may have access to the electronic safe system.

(4) Only a pharmacist, pharmacy technician, certified pharmacy technician or intern may stock drugs in the electronic safe system.

(5) All activities involving the electronic safe system must comply with all applicable state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165 & 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

DIVISION 42

NUCLEAR PHARMACIES AND PHARMACISTS

855-042-0005
Purpose and Scope

(1) Any person who provides radiopharmaceutical services shall be a nuclear pharmacist or working under the supervision of a nuclear pharmacist and shall act in accordance with the State Board of Pharmacy and State Radiation Control Agency rules.

(2) These rules shall not apply to anyone who is an "authorized practitioner" as that term is defined in these rules.

(3) The requirements imposed by these nuclear pharmacy rules shall apply in addition to, and not in place of, any other requirements contained in rules of the State Board of Pharmacy, the State Radiation Control Agency, or any other state or federal agency.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

855-042-0010
Definitions

(1) A "Nuclear Pharmacy" is a pharmacy providing radiopharmaceutical services.

(2) "Nuclear Pharmacist" means a licensed pharmacist who has met the requirements of these rules regarding training, education, and experience, and has received a letter of notification from the board indicating the board recognizes the pharmacist, based on evidence submitted, as qualified to provide radiopharmaceutical services.

(3) "Radiopharmaceutical Services" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery or radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A "Radiopharmaceutical" is any substance defined as a drug in Section 201(g)(1) of the federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(6) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

(7) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) "Authorized Practitioner" means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

855-042-0015
Nuclear Pharmacies

(1) Every nuclear pharmacy shall have a nuclear pharmacist designated on the nuclear pharmacy registration as the pharmacist-in-charge who shall be responsible for the nuclear pharmacy's compliance with laws and rules, both state and federal, pertaining to the practice of nuclear pharmacy. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacy pharmacist-in-charge shall see that directives from the board are communicated to the owner(s), management, other pharmacists, and interns of the nuclear pharmacy. A pharmacist may be pharmacist-in-charge for no more than one nuclear pharmacy at any one given time.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradio-pharmaceuticals and shall be secured from access by unauthorized personnel. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency before approval of the registration.

(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with accepted professional standards of radiopharmaceutical quality assurance.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable rules of the state Board of Pharmacy, the State Radiation Control Agency and other state and federal agencies.

(5) For nuclear pharmacies handling radiopharmaceuticals exclusively, the State Board of Pharmacy may waive regulations pertaining to the pharmacy registration for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(6) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(7) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(8) Prescriptions or medication orders for radiopharmaceuticals shall include:

(a) The name of the practitioner and/or institution;

(b) The name of the radiopharmaceutical;

(c) The amount of radioactivity to be contained in millicuries, microcuries, or the SI equivalent at calibration;

(d) The date and time of calibration, and volume.

(9) In addition to any labeling requirements of the state Board of Pharmacy for nonradiopharmaceuticals, the outer container of any radiopharmaceutical to be dispensed shall also be labeled with:

(a) The prescription number and the patient's name (of the words "Physician Use Only" in the absence of the name of the patient);

(b) The standard radiation symbol;

(c) The words "**Caution — Radioactive Material**";

(d) The name of the radiopharmaceutical;

(e) The lot number;

(f) The amount of radioactive material contained in millicuries, microcuries, or their SI equivalent;

(g) If a liquid, the volume in milliliters;

(h) The requested calibration date and time; and

(i) Expiration date and/or time, if applicable;

(j) Specific concentration of radioactivity;

(k) The name and address of the practitioner and/or institution that ordered the radiopharmaceuticals.

(10) The immediate inner container of a radiopharmaceutical shall be labeled with:

(a) Standard radiation symbol;

(b) The words "Caution — Radioactive Material"; and

(c) The name and prescription number of the radiopharmaceutical;

(d) The prescription number;

(e) The name of the nuclear pharmacy;

(f) The date; and

(g) The amount of radioactive material in millicuries, microcuries, or their SI equivalent.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA (New Drug Application) approved radiopharmaceuticals to authorized persons if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and rules of the State Board of Pharmacy and State Radiation Control Agency.

(14) The nuclear pharmacy shall maintain a reference library commensurate with the level of radiopharmaceutical service to be provided and shall include, in addition to the requirements listed in OAR 855-041-0040;

(a) Oregon radiation control regulations;

(b) **CFR Title 10, Parts 0–199**, with current amendments; and

(c) **CFR Title 49, Parts 106–199**, with current amendments.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87; PB 1-1994, f. & cert. ef. 2-2-94

855-042-0025
Minimum Equipment Requirements

(1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the State Board of Pharmacy and Radiation Control Agency before approval of the license.

(2) The State Board of Pharmacy may, for good cause shown, waive rules pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

DIVISION 43

PRACTITIONER DISPENSING

855-043-0001 [Renumbered to **855-043-0005**]

855-043-0002
Definitions

In this division of rules:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient at the direction of the practitioner.

(2) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(3) "Formulary" means a list of drugs or a list of disease states or health conditions, or preventative measures such as immunization or birth control approved by the Board or by the Department of Human Services (DHS).

(4) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or DHS.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: PB 2-1992, f. & cert. ef. 3-26-92; PB 4-1992, f. & cert. ef. 8-25-92; Renumbered from 855-043-0120 by BP 1-2010, f. & cert. ef. 2-8-10

855-043-0003
Expedited Partner Therapy

(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by DHS to be appropriately addressed by EPT.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

855-043-0005
Practitioner Labeling

All drugs dispensed by a practitioner must be labeled with the following information:

(1) Name, address and telephone number of the practitioner;

(2) Date;

(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;

(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(5) Direction for use;

(6) Required precautionary information regarding controlled substances;

(7) Such other cautionary information as required for patient safety; and

(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drugs dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.

(9) Not withstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, ORS 689.505 & 2009 OL Ch 522
Hist.: PB 4-1992, f. & cert. ef. 8-25-92; Renumbered from 855-043-0001 by BP 1-2010, f. & cert. ef. 2-8-10

Non-Pharmacy Dispensing Drug Outlets
County Health Clinics

855-043-0110
Purpose and Scope

(1) A Registered Nurse who is licensed with the Oregon State Board of Nursing, and who is an employee of a local health department established under the authority of a county or district board of health may dispense a drug or device to a client of the health department for purposes of caries prevention, birth control, or prevention or treatment of a communicable disease.

(2) Such dispensing shall be pursuant to the order of a person authorized to prescribe a drug or device, and shall be subject to rules jointly adopted by the Board and DHS.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: PB 2-1992, f. & cert. ef. 3-26-92; BP 1-2010, f. & cert. ef. 2-8-10

855-043-0120 [Renumbered to **855-043-0002**]

855-043-0130
Drug Delivery and Control

(1) The health officer is responsible for the establishment of policies and procedures that include:

(a) Procedures for drug dispensing, storage, security, and accountability;

(b) Maintenance of all drug records required by federal and state law;

(c) Procedures for procurement of drugs.

(2) Dispensing:

(a) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing board or by a Registered Nurse;

(b) A drug must be dispensed in a container complying with the federal Poison Prevention Packaging Act unless the patient requests a non-complying container;

(c) A Registered Nurses may only dispense a drug listed in, or for a condition listed in, the formulary;

(d) Each drug that is dispensed must be labeled with the following information:

(A) Name of patient;

(B) Name of prescriber;

(C) Name, address, and phone number of the clinic;

(D) Date of dispensing;

(E) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(F) Directions for use;

(G) Initials of the person dispensing;

(H) Cautionary statements, if any, as required by law;

(I) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(e) A drug information fact sheet must accompany each drug dispensed from a county health clinic.

(3) Repackaged Drugs. A drug repackaged for dispensing must be in a container meeting USP standards and labeled to identify at a minimum:

(a) Brand name, or generic name and manufacturer;

(b) Strength;

(c) Lot number;

(d) Manufacturer's expiration date or an earlier date if preferable. An internal control number which references manufacturer and lot number may be used.

(4) Drug Security, Storage, and Disposal:

(a) In the absence of a dispensing practitioner or a Registered Nurse, drugs must be kept in a locked drug cabinet or drug room which is sufficiently secure to deny access to unauthorized persons. Only dispensing practitioners and Registered Nurses may have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.

(b) All drugs must be stored in areas which will assure proper sanitation, temperature, light, ventilation and moisture control as recommended by the manufacturer.

(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(5) Drug Records;

(a) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(A) Name of patient;

(B) Brand name of drug, or generic name and name of manufacturer or distributor;

(C) Date;

(D) Initials of person dispensing the prescription.

(b) All records of receipt and disposal of drugs must be kept for a minimum of three years;

(c) All records required by these rules or by federal and state law must be readily retrievable and available for inspection by the Board.

(6) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Stat. Auth.: ORS 689.205 & 689.605
Stats. Implemented: ORS 689.155, 689.505 & 676.350
Hist.: PB 2-1992, f. & cert. ef. 3-26-92; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; BP 1-2010, f. & cert. ef. 2-8-10; BP 4-2010(Temp), f. 5-3-10, cert. ef. 5-4-10 thru 10-30-10; Administrative correction 11-23-10

Nurse Practitioner Dispensing

855-043-0210
Purpose and Scope

The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:

(1) Documented review of content regarding safe dispensing listed below:

(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";

(b) The Drug Enforcement Administration Pharmacist's Manual (2004);

(c) OAR 851, division 56;

(d) ORS Chapter 689 and OAR chapter 855;

(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"

(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov. 2006); and

(g) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications

(2) Successful self examination as provided by the Board of Nursing on these materials.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 678.390 & 689.205
Stats. Implemented: ORS 689.205
Hist.: BP 3-2003(Temp), f. 12-29-03, cert. ef. 12-31-03 thru 6-28-04; BP 4-2004, f. 5-21-04 cert. ef. 6-1-04; BP 1-2010, f. & cert. ef. 2-8-10

Family Planning Clinics

855-043-0300
Purpose and Scope

(1) A practitioner who has been given dispensing privileges by their licensing board, or a Registered Nurse, who is an employee of a clinic that is registered with the Board and is supported by DHS for purposes of providing public health family planning services, may dispense drugs or devices to clients for the purpose of birth control, the treatment of amenorrhea, hormone deficiencies, urinary tract infections or sexually transmitted diseases.

(2) Such dispensing must be pursuant to the prescription of a person authorized to prescribe a drug or device, and is subject to rules jointly adopted by the Board and DHS.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 1-2010, f. & cert. ef. 2-8-10

855-043-0310
Drug Delivery and Control

(l) Policies and Procedures. The licensed facility is responsible for the following:

(a) Maintaining written policies and procedures for drug dispensing, storage, security, and accountability;

(b) Maintenance of all drug records required by federal and state law; and

(c) Establishing procedures for procurement of drugs.

(2) Dispensing:

(a) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(b) A drug must be dispensed in a containers complying with the federal Poison Prevention Packaging Act unless the patient requests a non-complying container.

(c) A prescription must be labeled with the following information:

(A) Name of patient;

(B) Name of prescriber;

(C) Name, address, and phone number of the clinic;

(D) Date of dispensing;

(E) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(F) Directions for use;
(G) Initials of the person dispensing;
(H) Cautionary statements, if any, as required by law; and
(I) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.
(d) The prescriber must verbally counsel the patient concerning all new medications and a drug information fact sheet must accompany all drugs dispensed from a family planning clinic.
(3) Repackaged drugs. Drugs repackaged for dispensing must be in a container meeting USP standards and labeled to identify at a minimum:
(a) Brand name, or generic name and manufacturer;
(b) Strength;
(c) Lot number; and
(d) Manufacturer's expiration date, or an earlier date if preferable. An internal control number which references manufacturer and lot number may be utilized.
(4) Drug security, storage, and disposal:
(a) In the absence of a physician, pharmacist, Registered Nurse, Clinical Nurse Specialist, or nurse practitioner, all drugs must be kept in a locked drug cabinet or drug room that is sufficiently secure to deny access to unauthorized persons. Only physicians, pharmacists, Registered Nurses, Clinical Nurse Specialists or nurse practitioners shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.
(b) All drugs must be stored in areas which will assure proper sanitation, temperature, light, ventilation, and moisture control as recommended by the manufacturer.
(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.
(5) Drug records:
(a) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:
(A) Name of patient;
(B) Brand name of drug, or generic name and name of manufacturer or distributor;
(C) Date of dispensing; and
(D) Initials of person dispensing the prescription;
(b) All records of receipt and disposal of drugs must be kept for a minimum of three years.
(c) All records required by these rules or by federal and state law must be readily retrievable and available for inspection by the Board.
(6) A consultant pharmacist must conduct and document an annual inspection of the clinic in accordance with the directions of the Board. The completed report form must be filed in the clinic, and be available to the Board for inspection for three years.
(7) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 2009 OL Ch 522
Hist.: BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 1-2010, f. & cert. ef. 2-8-10

DIVISION 44

CHARITABLE PHARMACIES

855-044-0001
Purpose

The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept donated drugs for distribution when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0005
Definitions

(1) "Charitable Pharmacy" means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.
(2) "Point-of-Contact" means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0010
Registration

(1) A facility may not operate as a charitable pharmacy unless it is registered as such with the Board and has paid the fee specified in Division 110 of these rules.
(2) The application for registration must be on a form provided by the Board and must include proposed policies and procedures and a description of the organization.
(3) Each location must be registered separately.
(4) An applicant for registration as a charitable pharmacy must name a point-of-contact for each registered location.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0020
Personnel

(1) A charitable pharmacy must have a licensed pharmacist. The pharmacist may also be the Point-of-Contact.
(2) A charitable pharmacy that is co-located with an existing registered pharmacy may name a pharmacist employed by the existing pharmacy as its pharmacist.
(3) A charitable pharmacy that is not co-located with an existing registered pharmacy and does not have a pharmacist on staff must employ a consultant pharmacist.
(4) The pharmacist must develop policies and procedures for:
(a) Receiving donated drugs;
(b) Security;
(c) Drug storage;
(d) Distribution of drugs;
(e) Record keeping;
(f) Disposal of unusable drugs; and
(g) Staff training.
(5) The pharmacist must conduct a visual inspection of each donated drug to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging, and that based on this inspection and on the accuracy of the Donor's Form, the drug is safe to distribute.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0030
Drug Donation

(1) A charitable pharmacy may not accept:
(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;
(b) A non-prescription drug;
(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL.
(2) A charitable pharmacy may accept:
(a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and
(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.
(3) The following are examples of acceptable packaging:
(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

(7) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0040
Storage and Security

(1) A charitable pharmacy must store all donated drugs securely and physically separate from any existing inventory.

(2) All charitable pharmacy records must be secured to comply with HIPAA and all state and federal regulations.

(3) Outdated and unusable drugs intended for destruction must be quarantined and stored securely.

(4) A charitable pharmacy co-located with an existing pharmacy must use storage and record keeping procedures that maintain separation of charitable pharmacy records and drugs from other pharmacy records and inventory.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0050
Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

(b) Has not been stored in accordance with manufacturer's recommendations;

(c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;

(d) Bears an expiration date that is less than nine months from the date the drug is donated;

(e) Is adulterated or misbranded;

(f) Is a controlled substance;

(g) Is a drug that requires a special registration for dispensing;

(h) Is an over-the-counter drug;

(i) Requires specialty storage or handling;

(j) Requires refrigeration;

(k) Is a compounded drug; or

(L) In the pharmacist's professional judgment, may be unfit for dispensing.

(2) A charitable pharmacy may only dispense a drug to a person who:

(a) Has a valid prescription for the drug; and

(b) Is a resident of Oregon; and

(c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or

(d) Is enrolled in a program of public assistance as defined in ORS 411.010;

(3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:

(a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and

(b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.

(4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

(a) The prescription drug was donated to the program;

(b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;

(c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;

(d) Participants in the program are immune from liability as provided in ORS 689.780; and

(e) That they are qualified to receive the drug as specified in section (2) of this rule.

(6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0060
Labeling

(1) The label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:

(a) The name, address and telephone number of the pharmacy;

(b) The name of the prescribing practitioner;

(c) The initials of the dispensing practitioner;

(d) Date dispensed;

(e) The name of the patient;

(f) Name and manufacturer of drug, drug strength, the quantity dispensed;

(g) Direction for use;

(i) The expiration date;

(j) A unique identifier; and

(k) Any further cautionary information required for patient safety.

(2) All original patient identification must be removed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0070
Records

(1) A charitable pharmacy must maintain a donation record of all drugs received that includes:

(a) Donor's name and address;

(b) Drug manufacturer, lot number, name and strength;

(c) Drug quantity;

(d) Expiration date of the drug;

(e) Date donated; and

(f) The unique identifier.

(2) A charitable pharmacy must maintain a distribution and dispensing record that includes:

(a) Drug name and strength;

(b) Quantity distributed;

(c) Name of manufacturer;

(d) Lot number and expiration date;

(e) Date of distribution or dispensing;

(f) Name and address of recipient.

(3) A charitable pharmacy must maintain a record of all drugs that are destroyed.

(4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.

(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board and submitting it with their application for renewal of registration.

(6) All records required by these rules must be retained for three years and made available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0080
Fees

(1) A charitable pharmacy may not charge a fee for accepting a donation.

(2) A charitable pharmacy may not sell a donated drug.

(3) A charitable pharmacy may charge a dispensing fee that does not exceed two and a half times Oregon's current Medicaid dispensing fee.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0090
Liability

In accordance with ORS 689.780, a person who accepts or distributes donated prescription drugs through the charitable pharmacy program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774 & 689.780
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

DIVISION 45

STERILE AND NON-STERILE COMPOUNDING

855-045-0200
Application

(1) These rules (OAR 855-045-0200 to 855-045-0270) apply to any person, including any business entity, located in Oregon that engages in the practice of compounding drugs, or any person, including any business entity, located in any other state that compounds drugs for the use of patients located in Oregon. Compounding of radiopharmaceuticals is specifically exempted from these rules where these rules are in conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the Radiation Protection Services of the Oregon Department of Human Services or any other applicable agency. Any person located outside Oregon that compounds drugs for the use of patients located in Oregon is expected to follow the compounding rules of their home state or these rules, whichever are more stringent.

(2) These rules apply to sterile and non-sterile compounding of medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner – patient relationship.

(3) Whilst the Board does not insist on rigid application of, or adherence to, all the guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP 795) and 797 (USP 797), it expects pharmacists engaging in compounding to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of USP 795 and USP 797.

(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with OAR 855-060-0001, with the following exceptions:

(a) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-0005;

(b) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a routine, regularly observed pattern;

(c) Notwithstanding any other provisions of this rule, the preparation of a patient specific product utilizing all non-sterile commercial components, as defined in these rules as Category 1 compounding, is not considered compounding under these rules provided that:

(A) Preparation of these products is an infrequent occurrence;

(B) Quantity of product prepared does not exceed the requirements of a single prescription except that small quantities can be prepared upon request for in-office use by licensed practitioners.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-045-0210
Definitions

As used in this division of administrative rules:

(1) "Airborne Particulate Cleanliness Classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). The levels used in these rules are:

(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air.

(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air.

(c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.

(2) "Beyond Use Date" (BUD) means the date after which the preparation may not be dispensed or administered to a patient. BUD has the same meaning as "Expiration Date".

(3) "Biological Safety Cabinet" (BSC) means a ventilated cabinet with an inward airflow for personnel protection, a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection, and a HEPA filtered exhaust system for environmental protection.

(4) Categories of compounding: In these rules, compounding is defined as:

(a) Category 1: Nonsterile — Simple: Generally, the mixing of two or more commercial products. In these rules, this is not considered to be compounding.

(b) Category 2: Nonsterile — Complex: Generally, compounding with bulk drug substances or when calculations are required.

(c) Category 3: Sterile — Risk Level 1: Low-Risk, as defined in OAR 855-045-0250.

(d) Category 4: Sterile — Risk Level II: Medium-Risk, as defined in OAR 855-045-0250.

(e) Category 5: Sterile — Risk Level III: High-Risk, as defined in OAR 855-045-0250.

(5) "Compounding Aseptic Isolator" (CAI) means a glove box isolator with a microbially retentive HEPA air filter that maintains an aseptic compounding environment within the isolator throughout the compounding and material transfer process.

(6) "Compounded Sterile Preparation" (CSP) means:

(a) A preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in IV rooms; or

(b) A preparation containing nonsterile ingredients, or employing nonsterile components and devices, that must be sterilized before administration; or

(c) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injections, irrigations, metered sprays, and ophthalmic and otic preparations.

(7) "Compounding pharmacy" means any pharmacy where sterile or non-sterile compounding occurs on a regular basis.

(8) "Parenteral Admixture" means a sterile preparation that is the combination of one or more sterile products with an appropriate admixture vehicle.

(9) "Laminar Airflow Hood" (LAF) means a workspace where the work surface is subjected to a constant, HEPA filtered airflow that is directed towards the user.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-045-0220
Personnel

(1) Personnel who prepare compounded pharmaceuticals, both sterile and non-sterile, shall be provided with appropriate training before they begin to prepare such products including for CSPs, training in the theoretical principles and practical skills of aseptic manipulations.

(2) The pharmacist in charge (PIC) shall establish pharmacy Policies and Procedures that contain protocols in accordance with the guidelines in USP 797, for the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low and medium risk compounding.

(3) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually.

(4) The PIC shall ensure that training protocols are followed and records are kept for the training of all new personnel and for all continuing education and periodic testing that is completed.

(5) The PIC is responsible for the procedures and the overall operation of all activities within the pharmacy and must:

(a) Ensure all pharmacy personnel involved in preparing compounded products are trained and have demonstrated skills commensurate with the complexity of the procedures they are performing;

(b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accomplished by a review of each compounded product that includes but is not limited to:

(A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient;

(B) Verifying that the correct drugs and components were selected;

(C) Confirming that the calculation and quantity of each drug and component is correct;

(D) Verifying the label is correct and where appropriate contains all the information specified in OAR 855-041-0065 and these rules.

(c) Document verification by handwritten initials of the pharmacist responsible for the review.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-045-0230
General Requirements

A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has the duty to exercise that degree of care, skill, diligence and professional judgment that is used by ordinarily competent, careful pharmacists in the same or similar circumstances in the community of the pharmacist or a similar community.

(1) A pharmacist engaged in compounding shall:

(a) Conform to all relevant federal laws and rules;

(b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0200(4), and only when, in their professional judgment, it results from a valid prescriber-patient relationship;

(c) Compound only products that are not commercially available except as allowed in OAR 855-045-0240(2), and, except that with the prior approval of the Board, a commercial product that is temporarily in short supply or otherwise unavailable, may be compounded subject to OAR 855-045-0200(4)(c);

(d) Maintain all records in accordance with OAR 855-045-0270;

(e) Perform final product verification.

(2) The pharmacist-in-charge of a compounding pharmacy including a pharmacy that only prepares sterile parenteral products shall ensure that policies and procedures for that pharmacy are reviewed not less than annually, are available for all staff to refer to, and are complied with by all staff. The policies and procedures for a compounding pharmacy shall include but are not limited to, the following:

(a) An organized index;

(b) Product formula information;

(c) Specifications for a compounding log book in compliance with OAR 855-045-0270;

(d) Conditions and surveillance of the compounding environment;

(e) Compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks;

(f) Cleaning and equipment maintenance procedures;

(g) QA plan and documentation;

(h) Shipping and delivery procedures;

(I) Product labeling;

(j) Procedures for final product verification by the pharmacist;

(k) Compounded product quality procedures including procedures for establishing BUD;

(l) Training requirements for all staff;

(m) Safety procedures and training for personnel handling hazardous materials including:

(A) Use of personal protective equipment;

(B) Availability of Manufacturers' Safety Data Sheets;

(C) Emergency procedures related to spills, fire, or exposure to hazardous materials.

(n) Requirements for availability of reference materials.

(3) Pharmacies that compound sterile products including parenteral products shall, when appropriate, also include in their policies and procedures:

(a) Establishment of BUD;

(b) End Product Testing;

(c) Random sampling of both the environment and CSPs.

(4) The pharmacist-in-charge of a compounding pharmacy shall ensure that a quality assurance plan is written for that pharmacy and that:

(a) It includes record keeping requirements for cleaning, testing and calibration of all equipment and devices;

(b) Pharmacies that compound sterile products shall additionally include:

(A) Schedules and protocols for End Product Testing. Pharmacies mixing High Risk Level CSPs or extending Beyond Use Dating (BUD), must establish an End Product Testing schedule that includes random sampling. End Product Testing of a mixing process must show an acceptable sampling of the total preparations prepared annually;

(B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless a quality assurance program is established that verifies End Product Testing beyond the dating established by USP 797. Records to verify sterility and pyrogenicity must be maintained and available for review for three years.

(5) Bulk chemicals require a certificate of analysis.

(6) The labeling of bulk chemical containers shall contain:

(a) The date obtained;

(b) The BUD, which shall be established as specified in the pharmacy policies and procedures but not more than five years after opening unless additional testing is conducted to extend that BUD by not more than one year.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-045-0240
Sterile Parenteral Products

(1) In addition to complying with all the other rules in this chapter of rules that are appropriate to their practice setting, pharmacists compounding sterile parenteral products must comply with the following specific rules.

(a) Establish, maintain and enforce written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy. These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the practice setting and:

(A) Requirements for compounding, labeling and storage of the products;

(B) Requirements for administration of parenteral therapy;

(C) Requirements for storage and maintenance of equipment and supplies.

(b) Labeling: In addition to regular labeling requirements, the label shall include:

(A) Rate of infusion, as appropriate;

(B) Beyond Use Date;

(C) Storage requirements or special conditions, if applicable;

(D) Name, quantity and concentration of all ingredients contained in the products, including primary solution;

(E) Hand written initial of the pharmacist who verified the accuracy of the completed product.

(c) Patient Care Services: Counseling shall be available to the patient or patient's agent concerning proper use of parenterals and related supplies furnished by the pharmacy.

(2) In addition to complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may:

(a) Prepare multiple source commercially available premixed parenteral admixtures;

(b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral solution are commercially available;

(c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture that was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs;

(d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: PB 5-1987, f. & ef. 5-1-87; PB 12-1989, f. & cert. ef. 8-11-89; BP 7-2005, f. 12-14-05, cert. ef. 12-15-05; Renumbered from 855-041-0063, BP 2-2008, f. & cert. ef. 2-20-08

855-045-0250
Definitions of Risk Levels for Sterile Preparations

The three risk levels of CSPs recognized by USP 797 are based on the probability of contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels are defined, and products must be prepared and managed as follows:

(1) Low Risk Conditions:

(a) CSPs prepared using aseptic manipulation within an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components and devices;

(b) No more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;

(c) Manipulations limited to:

(A) Aseptically opening ampoules;

(B) Penetrating sterile stoppers on vials with sterile needles and syringes;

(C) Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing.

(d) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 48 hours at controlled room temperature;

(B) BUD up to14 days: under refrigeration;

(C) BUD up to 45 days: in solid frozen state at -20 °C.

(2) Medium Risk Conditions:

(a) CSPs compounded aseptically under Low-Risk Conditions but with the addition of one or more of the following conditions:

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;

(B) The compounding process includes complex aseptic manipulations other than single-volume transfer;

(C) The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.

(b) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 30 hours: at controlled room temperature;

(B) BUD up to 9 days: under refrigeration;

(C) BUD up to 45 days: in solid frozen state at -20 °C.

(3) High Risk Conditions:

(a) CSPs compounded from non-sterile ingredients, including products manufactured for other routes of administration, or a non-sterile device is employed before terminal sterilization;

(b) Exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:

(A) Sterile contents of commercially manufactured products;

(B) CSPs that lack effective antimicrobial preservatives;

(C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs.

(c) Prior to terminal sterilization:

(A) Nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;

(B) Compounding personnel are improperly gloved or garbed;

(C) Water-containing preparations are stored for more than 6 hours.

(d) In the absence of sterility testing:

(A) A preparation must be properly stored prior to administration as follows:

(i) For a BUD not to exceed 24 hours, at controlled room temperature;

(ii) For a BUD up to three days, under refrigeration;

(iii) For a BUD up to 45 days, in solid frozen state at -20 °C.

(B) All nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water then thoroughly drained or dried immediately before use;

(C) Terminal sterilization is required as follows:

(i) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter;

(ii) Sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron porosity filter entirely within an air quality environment better than or equal to ISO 5.

(4) Immediate-use:

(a) A compounded preparation intended for immediate use may be prepared in an air quality environment that does not meet ISO 5 or better conditions and a preparer is not required to wear gloves or gown, provided that it is prepared using aseptic manipulation, only sterile ingredients, products, components and devices are used, and it meets all of the following conditions:

(A) No more than three sterile ingredients, products, components and devices are used;

(B) Only simple manipulation techniques employed;

(C) The preparer completes the preparation without interruption and with no direct contact contamination;

(D) Administration must begin within one hour of preparation;

(E) If prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour BUD.

(b) Provided that such preparations do not involve the use of hazardous materials, they are classified as "Low Risk".

(5) "Same-day-use": In this rule, the term "Same-day-use" means that the administration of the preparation shall commence within 24 hours from the time of preparation. A same-day-use product that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile, ingredients, products, components and devices, may be classified as Low or Medium risk provided that it meets all the following conditions:

(A) Only simple manipulation techniques employed;

(B) The environment meets or exceeds the following conditions:

(i) The mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;

(ii) There is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet;

(iii) The buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process;

(iv) The environment is cleaned daily.

(C) The preparer completes the preparation without interruption and with no direct contact contamination;

(D) Batch preparation will not exceed eight CSPs;

(E) Administration of the preparation must begin within twenty-four hours of preparation;

(F) The preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown and mask.

(6) Single-dose vial.

(a) The BUD shall be no greater than one hour from time of initial entry if accessed in an environment worse than ISO 5;

(b) The BUD may be up to 24 hours from time of initial entry if appropriately stored and accessed only in an environment better than or equal to ISO 5;

(c) Medications in a single dose ampoule may not be reused.

(7) Multi-dose vial. The BUD may be up to one month or the manufacturer's assigned BUD whichever is shorter, from time of initial entry, in accordance with the pharmacy policies and procedures.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-045-0260
Pharmacies and Equipment

Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared.

(1) Pharmacies and equipment for the preparation of immediate-use CSPs shall be in accordance with OAR 855-045-0250(4).

(2) Effective January 1, 2009, for preparation of low-risk level CSPs, an ISO 5 certified or better Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CAI), or a Laminar Airflow Hood (LAF) shall be used.

(3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. These areas must have positive airflow unless used to prepare hazardous drugs. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.

(4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a positive air pressure of 0.02 to 0.05-inch water column and may not contain a sink or drain. Surfaces and essential furniture in buffer rooms and zones and anterooms shall be nonporous, smooth, nonshedding, impermeable, cleanable and resistant to disinfectants. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.

(5) Hazardous drugs must be prepared in compliance with state and federal regulations.

(6) Radiopharmaceuticals must be prepared in accordance with OAR 855-042-0005 through 0025.

(7) Pharmacy policies and procedures must include protocols for cleaning and monitoring that include:

(a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be performed at least daily. Floors in ISO 7 and 8 areas cleaned at least daily. Surfaces that are used to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant. Empty shelving, walls and ceilings in anterooms and buffer rooms will be cleaned at least monthly with appropriate disinfectant solution;

(b) All ISO classified areas will be checked and certified by a qualified individual no less than every 6 months and whenever the LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered;

(c) Maintenance, and documentation of maintenance, of all equipment in accordance with manufacturer's specifications.

(8) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

855-045-0270
Records

(1) Except for products prepared subject to OAR 855-045-0200(4)(c), all appropriate compounding logs, formula worksheets and documentation of the preparation, verification, dispensing or transfer of all compounded products must be stored in an organized manner, retained for a minimum of three years and be available for inspection by the Board.

(2) The formula worksheets for compounding pharmacies, excluding those for patient specific IV admixture products, must include but are not limited to the following:

(a) Drug name and strength;

(b) Quantity prepared;

(c) Date prepared;

(d) Pharmacy unique lot number;

(e) Manufacturers' lot numbers and expiration dates of all ingredients used to prepare compounded product;

(f) Beyond Use Date;

(g) Name of verifying pharmacist;

(h) Names of all technicians involved in the process;

(I) Copy of the label used for the compounded product;

(j) Mixing instructions;

(k) Physical evidence of the proper weight of each dry chemical or drug used;

(l) Pharmacist verification that the correct formula and the correct weights or volumes of chemical or drugs were used;

(m) Certification of completion of any additional testing, including endotoxin, required by the pharmacy's policies and procedures;

(n) Any other information required by the pharmacy's policies and procedures.

(3) Record of maintenance and certifications for all equipment must be retained for a minimum of three years and be available for inspection by the Board.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

DIVISION 50

RESTRICTION ON RETAIL SALES

855-050-0035
Over-the-Counter Drug Restrictions

(1) The following items shall be sold only by or under the direct supervision of a licensed pharmacist in registered pharmacies. They need not bear the store name and address, if in original container, need not be registered, but must be properly labeled. They shall not be available by self-service, but stored in or immediately adjacent to the prescription department. Items bearing prescription legend are excepted and may be sold only on prescription:

(a) Ammoniated Mercury ointment, five percent;

(b) Sulfa drugs — Alone or in combination;

(c) Blue Ointment.

(2) The following items shall be sold only by a licensed pharmacist(s) in registered pharmacies, must bear the store name and address, must be properly labeled with adequate warning, must be registered in Official Poison Register, and the purchaser must provide acceptable identification, providing the preparations do not bear prescription legend, in which case they may be sold only on prescription:

(a) Arsenic and its preparations;

(b) Corrosive sublimate;

(c) Cyanides and preparations, including hydrocyanic acid;

(d) Hydrochloric acid and any preparation containing free or chemically unneutralized hydrochloric acid (HC1) in a concentration of ten percent or more;

(e) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO_3) in a concentration of five percent or more;

(f) Sulphuric acid and any preparation containing free or chemically unneutralized sulphuric acid (H_2S0_4) in a concentration of ten percent or more;

(g) Solution of ammonia, U.S.P. 28 percent;

(h) Carbolic acid.

Stat. Auth.: ORS 689

Stats. Implemented:

Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 2-1979(Temp), f. & ef 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 4-1988, f. & cert. ef. 7-5-88; BP 6-2004(Temp), f. 10-15-04 cert. ef. 11-1-04 thru 5-13-05; Administrative correction 5-20-05

Pseudoephedrine

855-050-0045
Organic Silver Salts

(1) May be sold only by licensed pharmacists in registered pharmacies.

(2) Solutions must be freshly prepared, unless stabilized.

(3) Must be adequately labeled, to include name and address of store, date of preparation, and percentage content.

Stat. Auth.: ORS 689

Stats. Implemented:

Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-050-0070
Prescription Drugs

(1) The following are prescription drugs:

(a) Drugs required by federal law to be labeled with either of the following statements:

(A) "Caution: Federal law prohibits dispensing without prescription"

(B) "Caution: Federal law restricts this drug to be used by or on the order of a licensed veterinarian"; or

(C) "Rx only"

(b) Drugs designated as prescription drugs by the Oregon Board of Pharmacy

(2) The Oregon Board of Pharmacy designates the following drugs as prescription drugs:

(a) Preparations containing codeine or salts of codeine

(b) Preparations containing opium/paregoric

(3) No person shall sell, give away, barter, transfer, purchase, receive or possess prescription drugs except upon the prescription of a practitioner.

(4) The following are exempt from the prohibition of section (3) of this rule:

(a) Manufacturers

(b) Wholesalers;

(c) Institutional and retail drug outlets;

(d) Practitioners.

(5) Individuals who purchase, receive, or possess a prescription drug for the purpose of administration or delivery to a patient are exempt from the prohibition against purchasing, receiving, or possessing prescription drugs contained in section (3) of this rule and ORS 689.765(6).

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.765

Hist.: PB 3-1990, f. & cert. ef. 4-5-90; PB 9-1990, f. & cert. ef. 12-5-90; PB 4-1991, f. & cert. ef. 9-19-91; BP 1-2002, f. & cert. ef. 1-8-02; BP 7-2004, f. & cert. ef. 11-8-04; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 14-2006(Temp), f. 12-29-06, cert. ef. 1-1-07 thru 6-29-07; BP 1-2007, f. & cert. ef. 6-29-07

DIVISION 60

PHARMACEUTICAL MANUFACTURERS

855-060-0001
Application

No place of manufacturing, wholesaling or repackaging of drugs or medicines, as defined in ORS 689.005(20), (35), and (36) shall be conducted or operated until it has been registered by the State Board of Pharmacy, except that compounding or repackaging, as a part of a Shared Pharmacy Services agreement as defined in OAR 855-006-0005(20), does not constitute manufacturing. Manufacturing registration expires September 30th annually:

(1) All applications for registration of a new or relocated manufacturer shall be accompanied by the required fees as set forth in 855-110-0007(3).

(2) Application shall specify the location of the manufacturer premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner;

(a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the five largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(c) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(3) All registration renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (2)(a), (b), and (c) of this rule.

(4) A change of ownership or location requires a new application, fee and registration within 15 days.

(5) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(6) The registration cannot be prorated.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.305, 689.315 & 689.325

Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; Administrative correction 5-23-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 12-2006, f. & cert. ef. 12-19-06

855-060-0005
General Provisions and Minimum Standards

In order to qualify for a manufacturing registration, the applicant shall meet certain minimum standards:

(1) Organization: The physical plant of the manufacturer shall be properly organized with adequate facilities and qualified personnel to operate the same under the direction of a technically trained or professionally competent supervisor:

(a) The production supervisor in charge shall be responsible to the proper administrative authority of the manufacturer for the developing, supervising, and coordinating of all the activities of the manufacturing plant so far as production techniques are involved;

(b) Departmentalization shall follow good administrative procedure integrated with the administration of the manufacturing firm in general;

(c) The organizational structure of the manufacturing operation may vary depending upon the size and character of the particular products manufactured. (It is not the intent of the minimum standard requirements set out in the rules herein provided to cast all manufacturers in the same mold, although it is their intent to assure the establishment of fundamental principles which will enable competent production with sufficient freedom to supply the demand for adequate pharmaceutical products.)

(2) Policies: The production supervisor in charge, with approval of the director or other proper administrative or executive authority of the manufacturer, shall initiate and develop rules and regulations pertaining to the manufacturing procedures of the firm or producer. Such policies and procedures established by rule and regulation shall conform with techniques currently practiced in the other pharmaceutical industries of a similar kind. (The spirit of the minimum standard requirements for licensees is one of helpful cooperation.)

(3) Personnel: The production supervisor in charge shall be a person adequately trained in the specialized functions required for manufacturing of pharmaceutical products and may be required to submit properly attested documents of proof of formal education qualifying him for this position. He shall have such assistants as the volume of work in the plant may dictate. The personnel shall also include such additional technically trained persons as the activities of the manufacturer may require to supply pharmaceutical service of the highest

quality. The adequacy of the personnel will be determined by the size and scope of the manufacturing operation.

(4) Facilities: Adequate pharmaceutical and administrative facilities shall be provided including particularly:

(a) Essential manufacturing equipment to process properly the products to be manufactured;

(b) An adequate, up-to-date library for information concerning drugs and pharmaceutical products;

(c) Refrigeration for storage of thermolabile products;

(d) Adequate floor space;

(e) Sanitary facilities, lighting, ventilation, and plant safety as prescribed by the Workers Compensation Department, the Occupational Safety and Health Division.

(5) Products Control: Pharmaceutical manufacturing operations require facilities for chemical, physical and usually biological and bacteriological testing. The extent of laboratory facilities required for products control depends upon the products to be manufactured, the specifications and standards they are required to meet, and the raw materials involved in their production. If the manufacturing process is not large enough to justify the maintenance of a products control staff, the manufacturer's samples or products shall be sent to a competent laboratory for control checking of the manufactured product.

(6) Manufacturing of drug substances shall be separated from manufacturing of food substances.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 23, f. 2-14-74, ef. 3-11-74; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-060-0010
Sanitation and Plant Safety

(1) The manufacturing plant, its equipment and facilities, shall be maintained in a clean and orderly condition.

(2) The physical facilities of the manufacturing plant, shall be maintained so as to conform with the laws of this state and the rules and regulations of the Workers Compensation Department, the Occupational Safety and Health Division, relating to sanitation and safety. (The provisions of this section shall be applicable to storerooms, toilets, washrooms, basements, and all other portions of the plant wherein business is conducted.)

(3) Toilet and washroom accommodations shall be maintained separately and distinct from the manufacturing facilities. The doors to toilet and washroom accommodations shall at all times remain closed, except as a means of ingress or egress.

(4) The walls, ceilings, windows, and floors of the manufacturing plant shall be clean and maintained in good repair.

(5) The manufacturing plant shall be well lighted, ventilated, and kept free of obnoxious odors.

(6) No waste materials shall be permitted to collect upon the floors, counters, or other portions of the manufacturing plant. Waste receptacles shall be placed in convenient places for disposal of waste materials.

(7) No merchandise shall be stored in toilets or washrooms or be permitted to stand or to be stored or placed in any portion of the manufacturing plant except in a storeroom. Storerooms shall be maintained at a cool temperature, shall be dry and ventilated, free from rodents, insects, obnoxious odors, and shall be equipped with adequate lighting facilities. Merchandise shall be arranged in an orderly manner.

(8) The plumbing of the manufacturing plant shall be maintained in good repair.

(9) Equipment and materials necessary for processing or producing items to be manufactured shall be maintained in an orderly and clean condition. All instruments and equipment shall be thoroughly cleansed following use.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 33, f. 2-14-74, ef. 3-11-74; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-060-0015
Classification of Manufacturers

(1) Class I. A Class I manufacturer is required to employ an Oregon licensed pharmacist or a person approved by the Board who by experience and education possesses the necessary qualifications to supervise manufacturing procedures for United States Pharmacopeia, National Formulary, Accepted Dental Remedies products and including the manufacture of other internal medicines, controlled substances, dangerous external preparations, injectables, products requiring the prescription legend, poisons, and pure (U.S.P. and N.F. chemicals).

(2) Class II. A Class II manufacturer is required to employ personnel with a Bachelor of Science degree or equivalent, but not necessarily a licensed pharmacist to supervise manufacturing procedures, which are limited to non-toxic external preparations intended for preventative medication including antiseptics, germicides, detergents, or other agents intended for use in sanitation and not regulated by some other state agency.

(3) Class III. Repackagers or distributors of non-legend drugs will not be required to have a licensed pharmacist in charge, but will be required to have competent supervisory personnel.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 33, f. 2-14-74, ef. 3-11-74; 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-060-0020
Qualifications of Manufacturing and Wholesaling Personnel

(1) Only qualified personnel shall be employed to manufacture products.

(2) No drugs or medical supplies shall be manufactured in this state except under the personal supervision of a licensed pharmacist, chemist, or other person qualified by scientific or technical training or experience to perform such duties of supervision, as may be necessary, to protect the public health and safety. The manufacture of drugs and medicines shall be limited to persons having the necessary professional and/or technical qualifications and such persons may be required to submit properly attested documents of proof of formal education qualifying them for these positions.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 33, f. 2-14-74, ef. 3-11-74; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-060-0025
Labeling

(1) All stocks and materials, as well as products produced, shall be labeled and conform to the strength and purity as required by law.

(2) A sample label of each product manufactured shall be supplied to the State Board of Pharmacy upon request.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 33, f. 2-14-74, ef. 3-11-74; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80

855-060-0027
Identification of Prescription Drugs

(1) All prescription drug products in tablet or capsule form intended for oral administration will be required to be specifically identified. These drug products, when sold or distributed in Oregon after January 1, 1983, must be marked by the manufacturer with a code imprint identifying the drug product and the manufacturer or distributor of the drug product.

(2) "Code imprint" means an individual symbol, number, company name, words, letters, marking, National Drug Code, or any combination thereof, identifying the drug product and the manufacturer or distributor of the drug product.

(3) Exceptions to the requirement are:

(a) Drug products purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held for resale;

(b) Drug products which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed;

(c) Drug products which are used for experimentation or research purposes;

(d) The Board of Pharmacy, upon application of a manufacturer or distributor, may also exempt a particular drug product from the requirements of this regulation on the grounds that imprinting is not feasible because of such drug product's size, texture, or other unique characteristics.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 2-1981, f. & ef. 8-20-81

855-060-0029
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1992, f. & cert. ef. 1-31-92

855-060-0035
Registration of Mobile Manufacturers

(1) A mobile manufacturer means a manufacturer who manufactures within a vehicle equipped to provide unit dose packaging and repackage capabilities operated by a currently licensed pharmacist in this state.

(2) Stock medication for packaging and repacking will be furnished by the purchaser and shall exclude controlled substances.

(3) The vehicle shall be secure against pilferage, maintained and operated in accordance with good manufacturing practices standards in this division.

(4) All unit dose packages must be labeled in conformity with ORS 689.005.

(5) Records shall be maintained of all package operations of receipt and disposition of drugs.

(6) The building in which this vehicle is stored shall be its permanent address and shall maintain security of vehicle.

(7) Vehicle shall be registered annually; registration shall expire annually on July 1, of each year.

(8) Applicant must show to the Board that he will be actively in charge of equipment in this vehicle at all times it is in operation.

(9) If so required, the vehicle shall be registered with the federal Food and Drug Administration.

(10) The vehicle shall not display insignia or device to indicate that drugs are stored within or represent it as a pharmacy.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94

DIVISION 62

DRUG DISTRIBUTION AGENT

855-062-0003
Application

(1) Any person who is involved in the manufacture or wholesale distribution of a drug that is intended for distribution, dispensing or administration in Oregon, but who does not at any time have possession of any of the Active Product Ingredients (API) or the final product, and does not participate in the actual manufacturing process, must register under these rules as a Drug Distribution Agent, except that any such person, registered with the FDA as a manufacturer, who is accountable to the FDA for the purity and integrity of a drug must register as a manufacturer under Division 60 of this chapter of rules.

(2) The following persons must register as a Drug Distribution Agent under this division of rules:

(a) A broker;

(b) An import broker;

(c) An agent for a foreign manufacturer who is registered with the FDA;

(d) Sales and marketing office for a drug;

(e) A Drug Order Contractor;

(f) A person registered with the FDA as the holder of a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) that contracts with a third-party for the manufacture of a drug but does not take physical possession of the drug, does not have its name on the label and is not accountable to the FDA for the purity and integrity of the drug.

(3) Any person who would otherwise be required to register as a wholesaler under Division 65 of this chapter of rules but who does not at any time have possession of a drug intended for distribution must register as a Drug Distribution Agent under this division of rules.

(4) A person whose sole purpose is the marketing, brokering or arranging the initial distribution of drugs manufactured by a registered manufacturer, but does not take physical possession of a product must register as a Drug Distribution Agent.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0005
Definitions

(1) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the drug.

(2) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(3) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(4) "Drug": In this division of rules, the term "drug" shall mean any drug and any prescription device as these terms are defined in ORS 689.005.

(5) "Manufacturer" means any person, including a manufacturer's co-manufacturing partner, that is engaged in the manufacture of a drug, is responsible or otherwise accountable to the FDA for the manufacture of the drug, or is the private label manufacturer or distributor of product bearing its NDC number that is intended for sale, distribution, dispensing or administration in Oregon, and who holds one or more of the following registrations or licenses with the FDA:

(a) A New Drug Application number (NDA);

(b) An Abbreviated New Drug application number (ANDA);

(c) A Labeler Code number (LC) or National Drug Code Number (NDC);

(d) An FDA Central File Number (CFN);

(e) An FDA Establishment Identifier number (FEI);

(f) A Biologic License Application (BLA).

(6) "Manufacture" means the preparation, propagation, compounding, or processing of a drug or device intended for human or animal use. Manufacture includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(7) "Person" means individual, corporation, partnership, association, joint-stock company, business trust or unincorporated organization.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0020
Registration

(1) Any person engaged in any part of the process of manufacture or wholesale distribution of a drug into, out of, or within Oregon must be registered with the Board. A person must register as either:

(a) A manufacturer under Division 60 of this chapter of rules; or

(b) A wholesaler under Division 65 of this chapter of rules; or

(c) A Drug Distribution Agent under this division of rules.

(2) A person that is required to register as a Drug Distribution Agent must be registered before commencing business in Oregon and before any drug for which they provide a manufacturing, marketing or distribution service, may be sold, distributed, dispensed or administered in Oregon.

(3) A person that is required to register as a Drug Distribution Agent must apply for registration on a form provided by the Board and must provide information required by the Board that shall include but is not limited to:

(a) The name, business address, social security number or federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) Every trade or business name used by the applicant;

(c) Any disciplinary action taken by any state or federal authority against the applicant or any other distributor under common

ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(4) An applicant for renewal must complete the form provided by the Board and submit it to the Board with the appropriate fee by August 31 annually.

(5) An applicant that provides a manufacturing or distribution service in respect of a controlled substance as defined in Division 80 of this chapter of rules must also complete and submit the Controlled Substance registration form provided by the Board, with the appropriate fee.

(6) The Board may require a criminal history and financial background check of each principal, owner or officer of the applicant prior to initial registration and prior to any renewal unless the applicant is publicly traded. Any such checks shall be at the applicant's expense.

(7) The Board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(8) Each separate business entity and each location that does business in Oregon must be separately registered by the Board.

(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but is not limited to:

(a) Change of ownership;

(b) Change of business address;

(c) Any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers.

(10) The registration certificate is issued to a specific person and is non-transferable. Any addition or deletion of an owner or partner constitutes a change of ownership.

(11) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0030
Minimum Qualifications

The Board may deny an application for registration or renewal of registration as a Drug Distribution Agent on any of the following grounds:

(1) The applicant has been found by the Board or by a court to have violated the pharmacy or drug laws or rules of this state or of any other state, or of the federal government;

(2) The applicant has a history of non-compliance with state or federal rules or laws regulating the manufacture, distribution, or dispensing of drugs;

(3) The applicant has made a material misrepresentation to the Board in the course of applying for an initial or renewal of registration;

(4) Disciplinary action has been taken by the federal government or by any state, or local government regarding any license or registration currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs;

(5) The applicant has engaged in any conduct involving moral turpitude;

(6) The Board determines that granting the registration is not consistent with the public health or safety or is otherwise not in the public interest.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0040
Record Keeping

(1) A Drug Distribution Agent must establish and maintain records of all transactions regarding the distribution or other disposition of a drug. These records must comply with all federal drug laws and regulations and must include the following information:

(a) The source of the drug, including the name and physical address of the seller or transferor and any broker or other person involved in the transaction, the address of the location from which the drug was shipped and the address of the location to which the drug was shipped;

(b) The name, dose and quantity of the drug distributed;

(c) The date of distribution or other disposition of the drug.

(2) Records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, authorized law enforcement agencies, and this Board.

(3) Records required under these rules must be maintained for three years.

(4) Records required under these rules that are less than 13 months old must be kept at the address of record or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by these rules must be made available for inspection within three business days of a request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0050
Prohibited Practices

(1) The following practices are expressly prohibited:

(a) A Drug Distribution Agent may not participate in the purchase of a drug from a closed-door pharmacy;

(b) A Drug Distribution Agent may not participate in any way in the sale, distribution or transfer of a drug to a person who is required by the laws and rules of Oregon to be registered with the Board and who is not appropriately registered. Before authorizing or facilitating the distribution of a drug, a Drug Distribution Agent must verify that the person supplying or receiving the drug is appropriately registered with the Board.

(2) A Drug Distribution Agent may not perform, cause the performance of, or aid the performance of any of the following:

(a) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution;

(b) The adulteration, misbranding, or counterfeiting of a drug;

(c) The receipt of a drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the drug for pay or otherwise;

(d) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a drug or the commission of another act with respect to a drug that results in the drug being misbranded;

(e) The forging, counterfeiting, simulating, or falsely representing a drug using a mark, stamp, tag, label, or other identification device;

(f) The purchase or receipt of a drug from a person that is not registered to distribute drugs to the purchaser or recipient;

(g) The sale or transfer of a drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug, to purchase or receive drugs from the person selling or transferring the drug;

(h) The failure to maintain or provide records as required under these rules;

(i) Providing the Board, a representative of the Board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to these rules;

(j) Participating in the wholesale distribution of a drug that was:

(A) Purchased by a public or private hospital or other health care entity under the terms of an "own-use" contract; or

(B) Donated or supplied at a reduced price to a charitable organization; or

(C) Stolen or obtained by fraud or deceit; or

(D) Illegally imported into the USA.

(k) Facilitating the distribution or attempting to facilitate the distribution of a drug by fraud, deceit, or misrepresentation;

(L) Facilitating the distribution of a drug that was previously dispensed by a retail pharmacy or a practitioner;

(m) Failing to report an act prohibited by any of the rules in OAR Chapter 855 to the appropriate state or federal authorities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

DIVISION 65

WHOLESALE DRUG OUTLETS

855-065-0001
Application

(1) These rules (OAR 855-065-0001 to 855-065-0013) apply to any person, including any business entity, located in or outside Oregon that engages in the wholesale distribution of prescription or non-prescription drugs in Oregon except that a manufacturer that is registered under Division 60 of this chapter of rules does not also need to register as a wholesale distributor under these rules if they only distribute their own products or those manufactured by a Co-Manufacturing Partner as defined in OAR 855-065-0005.

(2) Any person that participates in the wholesale distribution of a drug but that does not at any time take physical possession or ownership of any drug must register as a Drug Distribution Agent in accordance with Division 62 of this chapter of rules, however a person that is registered with the Board as a manufacturer or a wholesaler does not also need to register as a Drug Distribution Agent.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); PB 1-1994, f. & cert. ef. 2-2-94; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-065-0005
Definitions

(1) "Authenticate" means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or

(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.

(3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the brokered substance.

(4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

(5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(7) "Common Carrier" means an organization that is available to the public to transport a product or service using its facilities, or those of other carriers.

(8) "Contraband Drug" means a drug that is counterfeit, stolen, misbranded, obtained by fraud, or purchased by an entity for its own use and placed in commerce in violation of an own-use agreement for that drug.

(9) "Cooperative Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and is owned, operated or affiliated with a group purchasing organization or pharmacy buying cooperative and distributes drugs exclusively to its members. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Cooperative Pharmacy Warehouse must also be listed as an Authorized Distributor of Record for that manufacturer.

(10) "Designated Representative" means an individual designated by each wholesale distributor registered by the Board who will serve as the primary contact person for the wholesale distributor with the Board and who is responsible for managing the company's operations at that registered location.

(11) "Drop Shipment" means a drug transaction whereby the manufacturer, that manufacturer's co-manufacturing partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor delivers a drug directly to a chain pharmacy warehouse, a cooperative pharmacy warehouse, a pharmacy, or other person authorized to administer or dispense prescription drugs to a patient, but transfers title to the drug to a wholesale distributor. A drop shipment shall be considered as part of a normal chain of distribution as defined in section (16) of this rule.

(12) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.

(13) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.

(14) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(15) "Manufacturer's Exclusive Distributor" means an entity, including a manufacturer's wholly owned distributor, that contracts with a manufacturer who is registered under Division 60 of this chapter of rules, to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and takes title to that manufacturer's drug, but does not have general responsibility to direct the drug's sale or disposition. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Manufacturer's Exclusive Distributor must also be listed as an Authorized Distributor of Record for that manufacturer.

(16) "Normal Chain of Distribution" means a chain of distribution, including a drop-shipment, for a prescription drug that goes from: a manufacturer; a manufacturer's co-manufacturing partner; a manufacturer's exclusive distributor; or a manufacturer's third-party logistics provider to:

(a) A pharmacy or a person authorized to administer or dispense a prescription drug to a patient; or

(b) A manufacturer's authorized distributor of record, to a pharmacy or a person authorized to administer or dispense a prescription drug to a patient; or

(c) A manufacturer's authorized distributor of record, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intra company pharmacy, to a patient or a person authorized to administer or dispense a prescription drug to a patient; or

(d) A chain pharmacy warehouse, to that chain pharmacy warehouse's intra company pharmacy, to a patient or a person authorized to administer or dispense a prescription drug to a patient; or

(e) A manufacturer's authorized distributor of record, to a specialty wholesaler, to a pharmacy or a person authorized to administer or dispense a prescription drug to a patient; or

(f) A manufacturer's authorized distributor of record to a cooperative pharmacy warehouse, to a member of the affiliated group purchasing organization or pharmacy buying cooperative, to a patient or a person authorized to administer or dispense a prescription drug to a patient.

(17) "Pedigree" means a statement or record in a written or electronic form that accurately records each wholesale distribution of a prescription drug from the sale by a manufacturer through acquisition and sale by any wholesale distributor or repackager until final sale to a pharmacy or other person authorized to administer or dispense the drug. The pedigree must include, but not be limited to, the following information for each transaction:

(a) The source of the prescription drug, including the name and principal address of the seller;

(b) The proprietary and established name of the prescription drug, the National Drug Code number, the amount of the prescription drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number or other unique shipping document number that identifies the transaction, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(c) The business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug.

(18) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(19) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the product to a patient.

(20) "Specialty Wholesale Distributor" means an entity that exclusively distributes a limited product line of drugs to a specific group of pharmacies or registered practitioners as approved in writing by the Board. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Specialty Wholesale Distributor must also be listed as an Authorized Distributor of Record for that manufacturer.

(21) "Third-Party Logistics Provider" means an entity that contracts with a manufacturer who is registered under these rules to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but does not take title to the drug or have general responsibility to direct the sale or disposition of the drug. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Third-Party Logistics Provider must also be listed as an Authorized Distributor of Record for that manufacturer.

(22) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.

(b) The sale of minimal quantities of a prescription drug by retail pharmacies to licensed practitioners for office use.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, including but not limited to transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.

(d) Intra company transfer of drugs as defined in these rules.

(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.

(f) The sale of a drug by a charitable organization described under 501(c)(3) of the Internal Revenue Code to a non-profit affiliate of the organization to the extent permitted by law.

(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.

(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.

(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.

(j) The sale, purchase, or trade of blood and blood components intended for transfusion.

(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a third-party returns processor or reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

(L) The transporting of a drug by common carrier where the common carrier does not take title to the drug and does not have responsibility to direct the drug's sale or distribution.

(m) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

(n) The distribution of drugs by a manufacturer registered under Division 60 of this chapter of rules of its own products to a person other than a patient.

(23) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs, including any entity whose business name appears on any invoice or other type of shipping document indicating possession or title. The term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors; independent wholesale drug traders; third-party logistics providers; cooperative pharmacy warehouses; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Wholesale Distributor must also be listed as an Authorized Distributor of Record for that manufacturer.

(24) "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons;

(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A) – (D) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer:

(A) Non-prescription drugs;

(B) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;

(C) Prescription devices that do not contain a prescription drug;

(D) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-065-0006
Registration Requirements

(1) Every wholesale distributor, wherever located, that engages in wholesale distribution into, out of, or within Oregon must be registered with the Board in accordance with the laws and regulations of Oregon before engaging in wholesale distribution of drugs. Every applicant for registration or renewal of registration must pay the appropriate fee in accordance with OAR 855-110-0007 and 855-110-0010. An applicant must register as a Class I Wholesaler or a Class II Wholesaler unless the applicant qualifies for registration as a Drug Distribution Agent under Division 62 of this chapter of rules.

(2) Application for registration must be on a form approved by the Board and must include, but not be limited to, the following information:

(a) The name, business address, social security number and federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) All trade or business names used by the applicant including any businesses outside Oregon;

(c) The names, addresses and telephone numbers of the designated representatives for all facilities used by the applicant that engage in wholesale distribution into, out of, or within Oregon;

(d) The normal business hours for the applicant; and

(e) Any disciplinary action taken by any state or federal authority against the applicant or any other wholesale distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(3) The Board may require a criminal history and financial background check of each principal, owner, officer and designated representative of the applicant prior to initial registration and prior to any renewal. Any such checks shall be at the applicant's expense.

(4) The Board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(5) Any wholesale distributor located outside the boundaries of Oregon, applying for registration or re-registration, as a Class I Wholesaler, must provide evidence of one of the following:

(a) A current license or registration as a wholesale distributor in a state that has a license or registration procedure approved by the Board that included a physical inspection within the past three years; or

(b) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service.

(6) Any wholesale distributor located inside the boundaries of Oregon, applying for registration or re-registration, as a Class I Wholesaler, must provide evidence of one of the following:

(a) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service; or

(b) That it is a small business as defined in ORS 183.310(10); and

(A) The applicant has no affiliation with any out-of-state pharmaceutical company; and

(B) All owners and principals of the applicant are Oregon residents; and

(C) No owner or principal, or close family member of an owner or principal, has a controlling or business interest in any other pharmaceutical company; and

(D) Neither the applicant, nor any of its owners or principals, has ever been found to be in violation of any drug law or regulation in this or any other state.

(7) In addition to the above registration requirements, an applicant for registration as a Class I wholesaler under this rule, that has not received VAWD accreditation, must provide evidence that it has obtained a bond or equivalent means of security of at least $100,000 that provides direct access to the Oregon Board of Pharmacy as a beneficiary to secure payment of any administrative penalties that may be imposed by the Board and any fees and costs that may be incurred by the Board and that:

(a) Are related to a registration held by the wholesale distributor; and

(b) Are authorized under Oregon law; and

(c) The wholesale distributor fails to pay less than thirty days after the penalties, fees, or costs become final.

(8) The Board may make a claim against a bond or security posted under section (7) of this rule within one year after the wholesale distributor's registration is no longer valid or sixty days after the conclusion of whichever occurs later:

(a) An administrative or legal proceeding before or on behalf of the Board that involves the wholesale distributor and results in penalties, fees or costs; or

(b) An appeal of such a proceeding.

(9) Where operations are conducted at more than one location by a single wholesale drug outlet, each such location that does business in Oregon must be registered by the Board.

(10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or designated representatives.

(11) The registration certificate is issued to a specific person and is non-transferable. Additions or deletions of an owner or partner shall be considered as a change of ownership.

(12) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in OAR 855-110-0007 within 15 days of the change.

(13) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-065-0007
Minimum Qualifications

The Board may deny an application for an initial registration or renewal of registration as a wholesale distributor on any of the following grounds:

(1) The applicant has been found by the Board or by a court to have violated the pharmacy or drug laws or rules of this state or of any other state or of the federal government.

(2) The applicant has been convicted of any offence under federal, state, or local laws.

(3) The applicant has a history of non-compliance with state or federal rules or laws regulating the manufacture, distribution, or dispensing of drugs.

(4) The applicant has made a material misrepresentation to the Board in the course of applying for an initial or renewal of registration.

(5) Disciplinary action has been taken by the federal government or by any state, or local government regarding any license or registration currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs.

(6) The applicant has engaged in any conduct involving moral turpitude.

(7) The Board determines that granting the registration is not consistent with the public health or safety or is otherwise not in the public interest.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.135, 689.155, 689.305, 689.315 & 689.405
Hist.: PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06

855-065-0009
Personnel

As a part of the registration or re-registration application, an applicant for registration as a Class I Wholesaler must name a Designated Representative (DR) for each wholesale distributor registered under these rules. The DR must:

(1) Be employed in a full-time managerial position by the wholesale distributor and may not be listed as the DR for more than one registrant without the specific written authority of the Board.

(2) Have at least two years verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale distributor registered under these rules or with another state.

(3) Have verifiable experience in record keeping and storage of prescription drugs.

(4) Be actively involved in and aware of the daily operations of the wholesale distributor.

(5) Be knowledgeable about all policies and procedures of the wholesale distributor.

(6) Be physically present at the wholesale distributor during normal business hours, which must be posted to be visible to the public, except when absent due to emergency, authorized absence or legitimate business reason (as used in this rule, "normal business hours" means at least six hours between 6.00 am and 7.00 pm on at least five days between Monday and Saturday every week, excluding national and local holidays). Class I wholesalers located within Oregon must designate a replacement DR and notify the Board accordingly, when any absence of the DR exceeds 15 days.

(7) The DR must conduct a self-inspection of the facility by September 1 each year, and document the results of this self-inspection on Oregon Wholesaler Self-Inspection Form provided by the Board. The DR must certify in writing, under penalties of perjury, that the information recorded on the Oregon Wholesaler Self-Inspection Form is correct. This form must be retained for three years and must be made available to the Board within two days upon request.

(8) The DR must ensure that the wholesale drug outlet has policies and procedures in effect and implemented to ensure that the outlet employs adequate personnel with the education and experience necessary to engage in the wholesale distribution of drugs safely and lawfully.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135, 689.305, 689.315

Hist.: PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06

855-065-0010
Minimum Requirements for Record Keeping and Inventory Management

(1) A Wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records must comply with all federal drug laws and regulations and must include the following information:

(a) The source of the drugs, including the name and physical address of the seller or transferor and any broker or other person involved in the transaction, the address of the location from which the drugs were shipped and the address of the location the drugs were shipped to;

(b) The identity and quantity of the drugs received and distributed or disposed of;

(c) The dates of receipt and distribution or other disposition of the drugs; and

(d) A pedigree as defined in OAR 855-065-0005(17) for any prescription drug that leaves the normal chain of distribution as defined by OAR 855-065-0005(16). All pedigrees initiated after January 1, 2009 must be in electronic form except that the Board may extend this date if it appears that the necessary technology is not adequately deployed across the pharmaceutical supply chain.

(2) Inventories and records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, law enforcement agencies, and this Board.

(3) Inventories and records required under these rules must be maintained for three years following disposition of the drugs.

(4) Records described in this section that are less than 13 months old must be kept at the inspection site or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by this rule must be made available for inspection within three business days of a request.

(5) A wholesale distributor must establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of drugs, including policies and procedures for identifying, recording, and reporting any loss, theft, counterfeiting or diversion of any drug and for correcting all errors and inaccuracies in inventories. A wholesale distributor must include in its written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a drug 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 a recall or withdrawal of a drug. Such procedure must be adequate to deal with a recall or withdrawal due to:

(A) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board;

(B) Any voluntary action by the manufacturer to remove a defective or potentially defective drug from the market; or

(C) Any action undertaken to promote public health and safety by replacing an existing drug with an improved product or new package design.

(c) A procedure to prepare for, protect against, and handle any crisis that affects the security or operation of the facility in the event of strike, fire, flood, or other natural disaster, or other local, state, or national emergencies.

(d) A procedure to ensure that any outdated drug is segregated from other drugs and either returned to the manufacturer or destroyed. This procedure must provide for written documentation of the disposition of an outdated drug. This documentation must be maintained for three years after disposition of the outdated drug.

(e) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(f) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband drugs and reporting of discrepancies within three business days to the Board and any other appropriate state or federal agency.

(g) Reporting of criminal or suspected criminal activities involving the inventory of drugs to the Board within three business days.

(h) Conducting for cause authentication as required under section (7) of this rule.

(i) Procedures for accurately documenting the temperature and humidity conditions of the storage facility.

(6) A wholesale distributor must maintain and adhere to written policies and procedures for all incoming and outgoing product shipments, including but not limited to the following:

(a) Upon receipt, visual examination of each shipping container sufficient to identify the drugs in the container and to determine whether the drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution.

(b) Upon receipt, review of records for accuracy and completeness, considering the:

(A) Total facts and circumstances surrounding each transaction involving the drugs; and

(B) Wholesale distributors involved.

(c) Quarantine of a drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution until:

(A) Examination and a determination is made that the drug is fit for distribution; or

(B) The drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(d) If the wholesale distributor determines that a drug is adulterated, misbranded, counterfeit, the wholesale distributor must provide notice of the adulteration, misbranding or counterfeiting to the Board, the Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the drug was acquired, within three business days.

(e) If the immediate or sealed outer or secondary container or labeling of a drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale distributor must:

(A) Quarantine the drug until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired; and

(B) Provide notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the Board, the Food and Drug Administration, and the manufacturer or wholesale distributor from which the drug was acquired, within three business days.

(f) A drug that is not adulterated, misbranded, counterfeit, or suspected counterfeit, but has been opened or used, is identified as such and quarantined until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(g) A drug that will be returned to a manufacturer or wholesale distributor is stored, handled and transported under proper conditions before the return, and documentation showing that proper conditions were maintained must be provided to the manufacturer or wholesale distributor to which the drug is returned.

(h) Inspection of each outgoing shipment to verify the identity of each drug and to ensure that each drug has not been damaged in storage or held under improper conditions.

(i) Contraband, counterfeit, or suspected counterfeit drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the Board or the Food and Drug Administration.

(j) Any sealed outer or secondary shipping container or labeling, and accompanying documentation, for a drug that is suspected to be counterfeit or fraudulent, is retained until a disposition is authorized by the Board and the Food and Drug Administration.

(k) Operations comply with all state and federal laws, rules and regulations applicable to wholesale drug distribution.

(l) All confidential information is stored in an area with restricted access and in such a way as to protect the integrity and confidentiality of the information.

(7) A wholesale distributor that has reason to suspect that a drug may be adulterated, misbranded, contaminated, contraband, counterfeit or otherwise unfit for distribution must conduct a "for cause" authentication of each distribution of the drug back to the manufacturer.

(8) A wholesale distributor that has engaged in the distribution of a drug for which a purchasing wholesale distributor conducts a "for cause" authentication must provide, upon request, detailed information regarding the distribution of the drug, including:

(a) The date of purchase of the prescription drug;

(b) The lot number of the prescription drug;

(c) The sales invoice number of the prescription drug; and

(d) Contact information, including name, address, telephone number, and electronic mail address of the wholesale distributor that sold the prescription drug.

(9) A wholesale distributor that purchases prescription drugs from another wholesale distributor must conduct a random authentication of at least 10 per cent of the pedigrees required under section (1)(d) of this rule, at least annually.

(10) If a wholesale distributor conducts an authentication of a drug pedigree, the wholesale distributor must maintain such records for three years and must produce the records for the Board and the Food and Drug Administration upon request.

(11) If a wholesale distributor conducts an authentication and is unable to authenticate each distribution of the prescription drug, the wholesale distributor must immediately quarantine the prescription drug and report the circumstances to the Board, and the Food and Drug Administration if applicable, not more than 10 business days after completing the attempted authentication.

(12) If the wholesale distributor is involved in the distribution of controlled substances, the distributor must register with the Drug Enforcement Administration and the Board, and comply with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances including, but not limited to, the isolation of controlled substances from non-controlled substances and storage of the controlled substances in a secure area in accordance with Drug Enforcement Administration security requirements and standards.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.315, 689.325 & 689.765
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06

855-065-0012
Storage of Drugs

(1) As a condition for receiving and retaining a wholesale distributor registration issued under these rules, an applicant must satisfy the Board that the applicant has and will continuously maintain acceptable storage and handling conditions and facilities standards for each facility at which drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which drugs are transported, including:

(a) Suitable construction of the facility and appropriate monitoring equipment to ensure that drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards.

(b) Suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.

(c) Adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(d) A quarantine area for the separate storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened.

(e) Maintenance of the facility in a clean and orderly condition.

(f) Maintenance of the facility in a commercial, nonresidential building.

(g) Freedom of the facility from infestation by insects, rodents, birds or vermin of any kind.

(2) The facility must be equipped with appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of drugs.

(3) The facility must meet security standards including but not limited to:

(a) Access controls that restrict access to areas where drugs are held, to authorized personnel.

(b) An after hours central alarm or a comparable entry detection system.

(c) Adequate outside perimeter lighting.

(d) Safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.305
Hist.: BP 12-2006, f. & cert. ef. 12-19-06

855-065-0013
Prohibited Practices

(1) The following practices are expressly prohibited:

(a) A wholesale distributor may not purchase drugs from a closed-door pharmacy.

(b) A wholesale distributor may not sell, distribute or transfer a drug to a person who is required by the laws and rules of Oregon to be registered with the Oregon Board of Pharmacy and who is not appropriately registered by the Board. Before furnishing a drug to any person not known to the wholesale distributor, the wholesale distributor must verify that the person is legally authorized to receive the drug.

(c) A wholesale distributor may not purchase any drug from a person who is required by the laws and rules of Oregon to be registered with the Oregon Board of Pharmacy and who is not appropriately registered by the Board. Before purchasing a drug from any person not known to the wholesale distributor, the wholesale distributor must verify that the person is legally authorized to sell the drug.

(d) A Class 1 wholesaler may not purchase any prescription drug from outside the normal chain of distribution, as defined by section 855-065-0005(16) without receiving an accompanying pedigree.

(e) A Class 1 wholesaler may not sell, distribute or transfer a prescription drug to another wholesale distributor, outside the normal chain of distribution as defined by section 855-065-0005(16), without providing a complete pedigree for the prescription drug.

(f) A Class 1 wholesaler who is classified as a "Specialty Wholesaler Distributor" as defined in OAR 855-065-005(20) may not:

(A) Sell, distribute or transfer a prescription drug to a pharmacy or to a practitioner who is licensed to prescribe the prescription drug, without providing a complete pedigree for the prescription drug, unless the prescription drug was purchased directly from the manufacturer or from the manufacturer's authorized distributor of record.

(B) Sell, distribute or transfer a prescription drug to a wholesale distributor, without providing a complete pedigree for the prescription drug.

(2) A wholesaler may not perform, cause the performance of, or aid the performance of any of the following:

(a) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.

(b) The adulteration, misbranding, or counterfeiting of a drug.

(c) The receipt of a drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the drug for pay or otherwise.

(d) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a drug or the commission of another act with respect to a drug that results in the drug being misbranded.

(e) The forging, counterfeiting, simulating, or falsely representing a drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

(f) The purchase or receipt of a drug from a person that is not registered to distribute drugs to the purchaser or recipient.

(g) The sale or transfer of a drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug, to purchase or receive drugs from the person selling or transferring the drug.

(h) The failure to maintain or provide records as required under these rules.

(i) Providing the Board, a representative of the Board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to these rules.

(j) Participating in the wholesale distribution of a drug that was:

(A) Purchased by a public or private hospital or other health care entity under the terms of an "own-use" contract; or

(B) Donated or supplied at a reduced price to a charitable organization; or

(C) Stolen or obtained by fraud or deceit; or

(D) Illegally imported into the USA.

(k) Obtaining or attempting to obtain a drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a drug.

(l) Failing to obtain, authenticate, or provide a required pedigree for a prescription drug.

(m) Receiving a prescription drug through wholesale distribution without receiving a required pedigree attested to as accurate and complete by the wholesale distributor.

(n) Distributing a drug that was previously dispensed by a retail pharmacy or a practitioner.

(o) Failing to report an act prohibited by any of the rules in OAR 855.065 to the appropriate state or federal authorities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 689.315 & 689.765
Hist.: BP 12-2006, f. & cert. ef. 12-19-06

DIVISION 70

PROPHYLACTICS AND CONTRACEPTIVES

855-070-0001
Definitions

(1) Prophylactic means a drug, device or medical preparation intended for or having special utility in the prevention of a sexually transmitted disease, or in the prevention of conception.

(2) Contraceptive means a drug, device or medical preparation intended for the prevention of conception.

(3) Male condom means a prophylactic or contraceptive device in the form of a sheath which completely covers the penis with a closely fitting membrane.

(4) Female condom means a prophylactic or contraceptive device in the form of an intravaginal pouch that consists of a sheath with a flexible ring on each end.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented:
Hist.: PB 1-1995, f. & cert. ef. 4-27-95

855-070-0005
Applications, Fees, and Licenses to Sell Prophylactics and Contraceptives

(1) Every wholesaler or manufacturer of prophylactics or contraceptives who distributes in Oregon goods of the class specified in ORS 435.010 shall annually submit an application for a license issued by the Board of Pharmacy:

(a) The application shall be made in writing on a form prepared by the Board and be accompanied by the fee listed in division 110;

(b) One such application shall be submitted and license obtained for each location or separate address from which goods are distributed;

(c) Licenses shall be issued upon receipt of the fee listed in division 110 and shall be in effect for one year from January 1 of each year. Licenses are not transferable;

(d) Licenses shall be publicly or conspicuously displayed and the wholesaler or manufacturer to whom they are issued shall be open to inspection by the Board or other authorized persons designated by the Board;

(e) Each application for a license shall include a list of all products or brands of prophylactics and contraceptives the applicant wishes to have approved for sale in the state.

(2) Before any condom product can be distributed in Oregon, it must be approved by the Oregon Board of Pharmacy. Every manufacturer or wholesaler that intends to distribute either male or female condoms shall furnish to the Board the names of such products.

(3) The Board may require proof to be furnished by the manufacturer or wholesaler that these products have received approval in accordance with the Federal Food, Drug and Cosmetic Act and regulations thereunder (Title 21 U.S.C. and CFR);

(4) The requirements under the Federal Food, Drug and Cosmetic Act and regulations thereunder (Title 21 U.S.C. and CFR) relating to prophylactics and contraceptives are adopted by reference and made a part hereof.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 435.010, 435.080, 435.100 & 689.155
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 29(Temp), f. & ef. 9-6-73; 1PB 32, f. 1-31-74, ef. 2-25-74; 1PB 35(Temp), f. & ef. 3-26-74; 1PB 36, f. 7-1-74, ef. 7-25-74; 1PB 39, f. & ef. 1-8-76; PB 10-1987, f. & ef. 12-8-87; PB 1-1995, f. & cert. ef. 4-27-95; BP 10-2006, f. & cert. et. 12-19-06

855-070-0010
Labeling and Storage of Prophylactics and Contraceptives

(1) The use of detachable slip labels or removable ink stamps listing names and addresses of manufacturer, brand name, and expiration date do not meet the labeling requirements of ORS 435.090.

(2) As of December 31, 1994, all prophylactics and contraceptives shall bear an expiration date. Prophylactics and contraceptives bearing an expiration date shall not be sold or otherwise distributed beyond that date.

(3) Prophylactics and contraceptives shall be stored, displayed, or sold from an area removed from excessive extremes of temperatures which may affect the quality of the products.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 29(Temp), f. & ef. 9-6-73 thru 1-3-74; 1PB 32, f. 1-31-74, ef. 2-25-74; 1PB 39, f. & ef. 1-8-76; 1PB 1-1984, f. & ef. 2-16-84; PB 1-1995, f. & cert. ef. 4-27-95

DIVISION 80

SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0015
Definitions

As used in these rules:

(1) "Act" means the Uniform Controlled Substances Act, ORS Chapter 475, and rules thereunder;

(2) "CFR" means Code of Federal Regulations;

(3) The term "registration" or variants thereof means the annual registration required of manufacturers, distributors and dispensers of controlled substances under ORS 475.125, and the term "registrants" or variants thereof refers to persons so registered; provided that where references of this nature are used in CFR sections referred to in these rules, the reference is to the registration requirements and registrants under the Federal Controlled Substances Act, and Title 21, CFR.

(4) "USC" means United States Code;

(5) Terms not defined in this rule have the definitions set forth in ORS 475.005.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035 & 475.940
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 5-1991, f. & cert. ef. 9-19-91; BP 3-2002(Temp), f. & cert. ef. 3-1-02 thru 8-23-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0020
Schedules

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 U.S.C. Sections 811 to 812 and as amended by the Board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; 1PB 2-1984, f. & ef. 3-7-84; 1PB 4-1984(Temp), f. & ef. 9-17-84; 1PB 1-1985, f. & ef. 2-27-85; 1PB 2-1985, f. & ef. 7-24-85; 1PB 4-1985, f. & ef. 12-2-85; 1PB 2-1986, f. & ef. 7-10-86; PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) Benzylfentanyl;

(b) Thenylfentanyl;

(c) N-Benzylpiperazine (BZP);

(d) 1,4-butanediol.

(e) Methamphetamine, except as listed in OAR 855-080-0022.

(2) Schedule I also includes the following substances, including their isomers, homologues, esters, ethers, salts, and salts of isomers, esters, and ethers except when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) CP 47,497 and homologues: 2-5-(2-methyloctan-2-yl)phenol).

(b) HU-210: also known as 6aR-trans-3-(1,1-Dimethylheptyl)-6a,7,10,10a-tetrahydro-1-hydroxy-6,6-dimethyl-6H-dibenzo pyran-9-methanol;

(c) JWH-018: 1-pentyl-3-(1-naphthoyl)indole, also known as Naphthalen-1-yl-(1-pentylindol-3-yl)methanone;

(d) JWH-073: 1-butyl-3-(1-naphthoyl)indole, also known as Naphthalen-1-yl-(1-butylindol-3-yl)methanone;

(e) JWH-200: 1-3-(1-naphthoyl)indole;

(f) JWH-081: 1-pentyl-3-(4-methoxy-1-naphthoyl)indole, also known as 4-methoxynaphthalen-1-yl- (1-pentylindol-3-yl)methanone;

(g) JWH-250: 1-pentyl-3-(2-methoxyphenylacetyl)indole, also known as 2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone.

(h) Any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.

(3) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals.

(b) 1,4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products.

(c) Marijuana.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059, 475.065 & 475.940
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 8-1987, f. & ef. 9-30-87; PB 10-1987, f. & ef. 12-8-87; PB 15-1989, f. & cert. ef. 12-26-89; PB 9-1990, f. & cert. ef. 12-5-90; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 4-2000, f. & cert. ef. 2-16-00; BP 9-2000, f. & cert. ef. 6-29-00; BP 2-2002(Temp), f. & cert. ef. 2-4-02 thru 7-31-02; BP 3-2002(Temp), f. & cert. ef. 3-1-02 thru 8-23-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 5-2002, f. & cert. ef. 11-14-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10; BP 10-2010(Temp), f. & cert. ef. 10-15-10 thru 4-11-11

855-080-0022
Schedule II

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.12 and any quantity of the following substances:

(1) Marijuana;

(2) Methamphetamine, when in the form of an FDA approved product containing methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059, 475.065
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 8-1987, f. & ef. 9-30-87; PB 10-1987, f. & ef. 12-8-87; PB 15-1989, f. & cert. ef. 12-26-89; PB 9-1990, f. & cert. ef. 12-5-90; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 3-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 4-2000, f. & cert. ef. 2-16-00; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0023
Schedule III

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.13; and

(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.

(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.

(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 11-1989, f. & cert. ef. 7-20-89; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); BP 3-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 4-2000, f. & cert. ef. 2-16-00; BP 9-2000, f. & cert. ef. 6-29-00; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0024
Schedule IV

Schedule IV consists of:

(1) The drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.14, unless specifically excepted or listed in another schedule: and

(2) Products containing carisoprodol or the salts of carisoprodol as an active ingredient.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 4-2000, f. & cert. ef. 2-16-00; BP 9-2000, f. & cert. ef. 6-29-00; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0026
Schedule V

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.15.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0028
Excluded Substances

The following drugs and their generic equivalents are excepted from the schedules in OAR 855-080-0021 through 855-080-0026:

(1) Benzedrex inhaler (Propylhexedrine).

(2) Vicks — Vapor inhaler (Levmetamfetamine).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 4-1987, f. & ef. 3-30-87; Renumbered from 855-080-0025; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1995, f. & cert. ef. 4-27-95; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 6-2006(Temp), f. & cert. ef. 8-25-06 thru 1-31-07; BP 8-2006, f. & cert. ef. 12-19-06; BP 8-2010, f. & cert. ef. 6-29-10

Registration of Manufacturers, Distributors and Dispensers

855-080-0031
Registration Requirements

Manufacturers, distributors, and pharmacies or other drug outlets are required to register with the Board under the Uniform Controlled Substances Act.

Stat. Auth.: ORS 689.155, 689.205
Stats. Implemented: ORS 475.125
Hist.: 1PB 6-1982, f. & ef. 8-6-82; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0050
Separate Registration for Places of Business

A separate registration is required for each principal place of business where controlled substances are manufactured or from which controlled substances are distributed or dispensed.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82

855-080-0055
Separate Registration for Independent Activities

The manufacturing and distributing of controlled substances are deemed activities independent of each other. A separate registration is required for each activity; however, a person registered to manufacture may distribute or dispense any controlled substance which they are registered to manufacture, provided that, unless specifically exempted, they comply with all requirements and duties prescribed by statute and rules for persons registered to distribute or dispense as applicable.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 475.125, 689.155
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0065
Security

(1) Applicants for registration and registrants must comply with the security requirements of 21 CFR 1301.02, 1301.71 through 1301.76 and 1301.90 through1301.93, which apply to their registration classification. The requirements of 21 CFR 1301.75 and 1301.76 relating to "practitioners" are applicable to applicants and registrants who are drug dispensers.

(2) The security requirements of subsection one of this rule apply to all "controlled substances," as defined in these rules, except ephedrine, pseudoephedrine and phenylpropanolamine.

(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine and phenylpropanolamine.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.135
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 5-1991, f. & cert. ef. 9-19-91; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0070
Records and Inventory

All registered persons shall, as applicable to the registration classification, keep records and maintain inventories in conformance with 21 U.S.C. Section 827; 21CFR 1304.02 through 1304.11; 1304.21 through 1304.26; 1304.31 through 1304.33; except that a written inventory of all controlled substances shall be taken by registrants annually within 365 days of the last written inventory. All such records shall be maintained for a period of three years.

Stat. Auth.: ORS 475.035, 689.205
Stats. Implemented: ORS 475.165
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; 1PB 1-1986, f. & ef. 6-5-86; PB 10-1987, f. & ef. 12-8-87; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1994, f. & cert. ef. 2-2-94; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0075
Order Forms

Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form in conformance with **21 U.S.C. Section 828** and **21 CFR 1305.01** through **1305.29**.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; PB 5-1991, f. & cert. ef. 9-19-91; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06

855-080-0080
Special Exceptions

The provisions of 21 CFR 1307.11 through 1307.13 are applicable under the Act.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; PB 5-1991, f. & cert. ef. 9-19-91; BP 1-2007, f. & cert. ef. 6-29-07

Controlled Substances Prescriptions

855-080-0085
Prescription Requirements

(1) Except as provided in sections (2) and (3) of this rule, the provisions of 21 CFR 1306.01 through 1306.27 and 1304.03(d) shall be complied with by the registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling dispensing, record-keeping and filing of prescriptions for controlled substances. An electronic prescription is permitted for any substance listed in OAR 855-080-0022 through 855-080-0026 when so permitted by federal regulations.

(2) The provisions of 21 CFR 1306.11(a) under section (1) of this rule are amended by deleting "which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act."

(3) The provisions of 21 CFR 1306.21 through 1306.27 under section (1) of this rule shall be deemed to apply also to controlled substances listed in Schedule V.

(4) Controlled substances in Schedules III, IV, and V which are prescription drugs determined by the Board pursuant to ORS 475.185(3) are those prescription drugs as determined under the Federal Food, Drug, and Cosmetic Act. Such drugs are "Legend Drugs" and bear the legend "Caution: Federal law prohibits dispensing without a prescription", or an equivalent legend. In addition, any preparation containing any amount of codeine or its salts, opium, or paregoric in Schedules III, IV, or V is a prescription drug as determined by the Board pursuant to ORS 475.185(3).

(5) "Emergency Situations" as referred to in ORS 475.185(2) mean the same as specified in 21 CFR 290.10.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.185, 475.188
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 15-1989, f. & cert. ef. 12-26-89; PB 5-1991, f. & cert. ef. 9-19-91; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0095
Verification of Research Registration

Persons conducting research with controlled substances in Sections I through V within this state who are not otherwise exempt from registration pursuant to ORS 475.125(3), may, upon furnishing the Board a copy of a current federal registration certificate issued for such a purpose, pursuant to ORS 475.135, receive written verification of such submission from the Board's Executive Director.

Stat. Auth.: ORS 475
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06

855-080-0100
Animal Euthanasia

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or regis-tration renewed to allow the purchase, possession and administration of sodium pentobarbital for euthanizing injured, sick, homeless or unwanted domestic pets and other animals:

(a) Storage. All supplies of sodium pentobarbital shall be kept in a locked cabinet. An assigned person designated in writing shall be responsible for the security of the sodium pentobarbital. Such designated person shall allow withdrawal of the drug only to a person certified by the Oregon State Veterinary Medical Examining Board to administer sodium pentobarbital;

(b) Records. The following records shall be made at the time of the occurrence and shall be maintained for a minimum of three years, available for inspection by the Board of Pharmacy and its agents:

(A) A record of the withdrawal of sodium pentobarbital, signed by the person who takes possession of the sodium pentobarbital for administration;

(B) A record of the weight, species of animal and dosage administered for euthanasia signed by the person who administers the drug and by the designated person responsible for security;

(C) A record of all wastage signed by the person administering the drug and the designated person responsible for security; and

(D) A weekly record of verification of the stock on hand, minus the amounts withdrawn for administration, signed by the designated person responsible for security;

(E) A record of disposal of any expired or unwanted sodium pentobarbital. Disposal shall be in a conformance with **21 CFR 1307.21**.

(c) Audits. The registrant shall submit to random audits of records and analysis of prepared solutions by the State Board of Pharmacy or its agents.

(2) The fee for registration shall be $25, paid annually by December 31 of each year.

(3) The Board will suspend or revoke the registration of any humane society or animal control agency which allows a person to administer sodium pentobarbital who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.:1PB 2-1984, f. & ef. 3-7-84; PB 9-1990, f. & cert. ef. 12-5-90; PB 5-1991, f. & cert. ef. 9-19-91

855-080-0105
Disposal of Drugs

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in conformance with **21 CFR 1307.21**.

(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the following:

(a) The consultant pharmacist or registered nurse designee.

(b) The Director of Nursing Services or supervising nurse designee

(c) The administrator of the facility or an administrative designee

(d) A Registered Nurse employed by the facility

(4) The destruction shall be documented and signed by the witnesses and the document retained at the facility for a period of at least three years. Copies of the document shall be sent to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.

(5) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.305
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1989, f. & cert. ef. 1-3-89; PB 1-1990, f. & cert. ef. 1-23-90; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1996, f. & cert. ef. 4-5-96; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 8-2010, f. & cert. ef. 6-29-10

DIVISION 90

AEROSOL SPRAYS

855-090-0005
Approved Aerosol Sprays for Legitimate Medical Use

(1) The Oregon State Board of Pharmacy finds that the following aerosol sprays are essential to their intended use for a legitimate medical purpose and pursuant to ORS 468.605, as amended. In addition to the aerosol sprays authorized to be sold or offered for sale by that statute, the following aerosol sprays may also be sold or offered for sale in the State of Oregon:

(a) Cortico Steroids and Combinations:
(A) Aristocort A Spray Lotion;
(B) Terra Cortril Topical Aerosol Spray;
(C) Aeroseb-Dex;
(D) Aeroseb-HC;
(E) Metiderm Aerosol;
(F) Metiderm with Neomycin;
(G) Metiderm with Neomycin Veterinary;
(H) Kenalog Spray;
(I) Respihaler Decadron;
(J) Turbinaire;
(K) Decaspray;
(L) Terra Cortril Spray;
(M) Neo Decaspray.
(b) Skin Preparation Materials:
(A) Vi Drape Adhesive;
(B) Aeroplast Dressing;
(C) Hollister Medical Adhesive;
(D) Frigiderm;
(E) All Aerosol Benzoin Preps;
(F) Hollister Medical Adhesive;
(G) Hollister Medical Adhesive Remover;
(H) Aerosolv;
(I) Uni-Solve Adhesive Remover;
(J) Uni-Solve Non-Inflamable Remover;
(K) Skin Prep Protective Dressing;
(L) Truett Benzocaine Spray;
(M) Truett Silicone Skin Spray;
(N) Truett Tape Remover;
(O) Granulex;
(P) Proderm;
(Q) Rezifilm;
(R) H & L Silicone Skin Protector;
(S) H & L Golden Spray Bandage;
(T) Silon.
(c) Topical Antiseptics:
(A) Obtundia;
(B) Burn Tame.
(d) Fungicides:
(A) Tinactin;
(B) Aftate Antifungal Powder;
(C) Aftate Antifungal Spray Liquid.
(e) Topical Anesthetics:
(A) Gebauer Fluori-Methane Spray;
(B) Gebauer Fluro-Ethyl Spray;
(C) Aero Therm;
(D) Aero Freeze;
(E) Aero Caine;
(F) Aerocaine — 5;
(G) H & L Skin Freeze;
(H) Burn Tame;
(I) Obtundia;
(J) Xylocaine Dental Spray;
(K) Solarcaine Spray;
(L) Amercaine Aerosol;
(M) Foille First Aid Spray;
(N) Dermoplast Aerosol Spray.
(f) Miscellaneous:
(A) Cryokwik;
(B) Medihaler Ergotamine;
(C) Spray-Cyte Cytological Fixative;
(D) Sulfamylon — N;
(E) Truett Aerostat;
(F) Pfizer Buffered Iodine Spray;
(G) Blue Lotion Aerosol;
(H) Screw Worm Aerosol;
(I) Pfizer Live Stock Spray;
(J) Pro-Fixx Aerosol;
(K) Fast-Freezz;
(L) Trypzyme-Burns Biotic;
(M) Fivex-Burns Biotic.

(2) The list of aerosol sprays stated in section (1) of this rule is subject to amendment upon the Board's finding that any listed aerosol spray no longer meets requirements for exemption under ORS 468.605, as amended. This includes a finding that an alternative non-prohibited propellant has been developed and approved for the product or a similar product. Sections (1), (2), and (3) of this rule expire by operation of ORS 468.605, as amended, on July 1, 1983.

(3)(a) A determination by the Board under ORS 468.605, as amended, that the use of an aerosol spray is essential to its intended use for a legitimate medical purpose, includes, but is not limited to, the following considerations:

(A) Whether the aerosol spray is necessary in terms of providing an important medical advantage not achieved by other forms of treatment or delivery;

(B) Whether the use of the prohibited propellant is necessary to achieve the aerosol spray in question, i.e.:

(i) Whether a pump or bulb spray would achieve the result for which the medical benefit is claimed;

(ii) If chemical aerosolization is necessitated over other forms of aerosolization, whether other non-prohibited chemical propellants would achieve the desired result, and if so, whether such chemical propellants are available and approved either for the product in question or for a similar product.

(b) With respect to dermatological preparations, the following conditions are examples where the Board has found aerosol sprays to provide an important medical advantage over other forms of treatment or delivery:

(A) Painful (touch-sensitive) skin conditions;
(B) Vesicular (blistered) skin conditions;
(C) Weeping, infected skin conditions;
(D) Ulcerated skin conditions;
(E) Disease in hairy areas;
(F) Disease in anatomically occluded areas (axillae, groin, etc.);
(G) Disease about surgical stomas.

Stat. Auth.: ORS 468
Stats. Implemented:
Hist.: 1PB 49(Temp), f. & ef. 2-25-77; 1PB 52, f. & ef. 5-19-77

DIVISION 110

FEES

855-110-0003
General

(1) All fees paid under these rules are non-refundable.

(2) Fees cannot be prorated.

(3) A delinquent fee must be paid:

(a) When an application is postmarked after the date specified in these rules; or

(b) When the Board requests additional information from an applicant and this information is not provided within 30 days.

(4) A delinquent fee may be assessed when an application is submitted incomplete and the Board requests the missing information.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-110-0005
Licensing Fees

(1) Pharmacist license examination (NAPLEX) and re-examination fee — $50.

(2) Pharmacist jurisprudence (MPJE) re-examination fee — $25.

(3) Pharmacist licensing by reciprocity fee — $200.

(4) Pharmacist licensing by score transfer fee — $200.

(5) Intern license fee. Expires November 30 every two years — $30.

(6) Pharmacist:

(a) License fee. Expires June 30 annually — $120. Delinquent renewal fee, (postmarked after May 31) — $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 annually — $25. (This is a mandatory fee, required by Chapter 799 Oregon Laws 2009 that must be paid with the pharmacist license renewal fee).

(c) Workforce Data Collection fee. Due by June 30 biennially — $5. (This is a mandatory fee, required by Chapter 595 Oregon Laws 2009 that must be paid with the pharmacist license renewal fee every two years commencing 2011).

(7) Certification of approved provider of continuing education course fee, none at this time.

(8) Pharmacy Technician license fee. Expires September 30 annually — $35. Delinquent renewal fee, (postmarked after August 31) — $20.

(9) Certified Pharmacy Technician:

(a) License fee. Expires September 30 annually — $35. Delinquent renewal fee, (postmarked after August 31) — $20.

(b) Workforce Data Collection fee. Due by September 30 biennially — $5. (This is a mandatory fee, required by Chapter 595 Oregon Laws 2009 that must be paid with the Certified Pharmacy Technician license renewal fee every two years commencing 2010).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135, OL 2009, Ch. 799 and 595
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. &ef. 4-3-80; 1PB 3-1980, f. 5-3-80, ef. 5-3-80 & 7-1-80; 1PB 2-1982, f. 3-8-82, ef. 4-1-82; 1PB 1-1984, f. & ef. 2-16-84; 1PB 3-1985, f. & ef. 12-2-85; PB 3-1988, f. & cert. ef. 5-23-88; PB 7-1989, f. & cert. ef. 5-1-89; PB 15-1989, f. & cert. ef. 12-26-89; PB 10-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 2-1997(Temp), f. 10-2-97, cert. ef. 10-4-97; BP 2-1998, f. & cert. ef. 3-23-98; BP 1-2001, f. & cert. ef. 3-5-01; BP 2-2001(Temp), f. & cert. ef. 7-26-01 thru 1-22-02; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 1-2006, f. & cert. ef. 6-9-06; BP 5-2006(Temp), f. & cert. ef. 8-25-06 thru 1-20-07; BP 9-2006, f. & cert. ef. 12-19-06; BP 5-2009, f. & cert. ef. 12-24-09; BP 5-2010(Temp), f. 5-3-10, cert. ef. 5-4-10 thru 10-30-10; BP 6-2010, f. & cert. ef. 6-29-10

855-110-0007
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) County Health Clinic (including family planning clinics). Expires March 31 annually — $75. Delinquent renewal fee (postmarked after February 28) — $25.

(2) Drug Distribution Agent. Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.

(3) Drug Room (including correctional facility). Expires March 31 annually — $75. Delinquent renewal fee (postmarked after February 28) — $75.

(4) Manufacturer. Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.

(5) Medical Device, Equipment & Gas Class C. Expires January 31 annually — $50. Delinquent renewal fee (postmarked after December 31) — $25.

(6) Nonprescription Class A. Expires January 31 annually — $50. Delinquent renewal fee (postmarked after December 31) — $25.

(7) Nonprescription Class B. Expires January 31 annually — $25. Delinquent renewal fee (postmarked after December 31) --$10.

(8) Nonprescription Class D. Expires January 31 annually — $100. Delinquent renewal fee (postmarked after December 31) — $25.

(9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer — $50. Expires December 31 annually.

(10) Re-inspection fee — $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(11) Retail or Institutional Drug Outlet. Expires March 31 annually — $175. Delinquent renewal fee (postmarked after February 28) — $75.

(12) Veterinary Drug Outlet, Expires September 30 annually — $00. Delinquent renewal fee (postmarked after August 31) — $00.

(13) Wholesaler. Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.

(14) Remote Dispensing Machine. Expires March 31 annually — $100. Due by February 28 annually.

(15) Charitable Pharmacy. Expires March 31 annually — $75. Delinquent renewal fee (postmarked after February 28) — $25.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135, 689.774
Hist.: PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 3-1998, f. & cert. ef. 3-23-98; BP 2-2001(Temp), f. & cert. ef. 7-26-01 thru 1-22-02; BP 1-2002, f. & cert. ef. 1-8-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 6-2010, f. & cert. ef. 6-29-10

855-110-0010
Fees for Registration for Controlled Substances under ORS 475.095

(1) Animal Euthanasia controlled substance registration fee — $25 annually.

(2) County Health Clinic (including family planning clinics) controlled substance registration fee — $25 annually.

(3) Drug Distribution Agent controlled substance registration fee — $50 annually.

(4) Drug Room (including correctional facility) controlled substance registration fee — $25 annually.

(5) Manufacturer controlled substance registration fee — $50 annually.

(6) Retail or Institutional Drug Outlet controlled substance registration fee — $25 annually.

(7) Schedule II Precursor registration fee — $25 annually.

(8) Wholesaler controlled substance registration fee — $50 annually.

(9) Remote Dispensing Machine controlled substance registration fee — $25 annually.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 6-1982, f. & ef. 8-6-82; 1PB 2-1984, f. & ef. 3-7-84; PB 15-1989, f. & cert. ef. 12-26-89; PB 10-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1996, f. & cert. ef. 4-5-96; BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-110-0015
Administrative Fees

(1) The Board of Pharmacy may charge a fee reasonably calculated to reimburse the agency for costs of providing and conveying copies of public records, and other administrative services.

(2) All fees and charges must be paid before public records will be available for inspection or copies provided.

(3) Costs include but are not limited to:

(a) The services and supplies used in making the records available;

(b) The time spent locating the requested records, reviewing the records, and redacting or separating material exempt from disclosure;

(c) Supervising a person's inspection of original documents;

(d) Copying records;

(e) Certified copies of records and licenses;

(f) Summarizing, compiling or organizing the public records to meet the person's request;

(g) Searching for and reviewing records even if the records subsequently are determined to be exempt from disclosure;

(h) Postal and freight charges for shipping the copies of the public records sent first class or bulk rate based on weight;

(i) Indirect costs or third party charges associated with copying and preparing the public records;

(j) Costs associated with electronic retrieval of records;

(k) Actual costs charged by the Attorney General's office for attorney's time spent in reviewing and redacting material from the records, and in separating material into exempt and nonexempt records. A fee may not be charged for the cost of time spent by an attorney in determining the application of the provisions of ORS 192.410 to 192.505;

(L) Staff time for performing the work;

(m) The cost of publications will be based on the actual costs of development, printing and distribution as determined by the Board;

(4) The Board shall establish and publish a list of fees used to charge requestors for the costs of preparing and making available the following and shall review the schedule at least once a biennium and any time an increase is proposed, to assure that the fees reflect current Board costs:

(a) Photocopies;

(b) Facsimile copies. The Board may limit the transmission to twenty pages;

(c) Electronic copies, CDs, DVDs, and other electronically generated materials including lists electronically mailed from the Board database. The Board shall determine what electronic media for reproduction of computer records may be used and whether the electronic media is to be provided by the Board or the requestor;

(d) Manual license verification;

(e) Publications including but not limited to:

(A) Copies of Laws and Rules;

(B) The newsletter.

(f) Licensee duplicate wall certificates;

(g) Duplicate renewal forms;

(h) Re-mailing of returned mail when a licensee or registrant has failed to notify the Board of a change of address.

(5) No additional fee may be charged for providing records or documents in an alternative format when required by the Americans with Disabilities Act.

(6) The Board shall notify requestors of the estimated fees for making the public records available for inspection or for providing copies to the requestor. If the estimated fees exceed $25, the Board shall provide written notice and may not act further to respond to the request until the requestor notifies the Board, in writing, to proceed with making the records available.

(7) The Board or its designee may reduce or waive any of the above administrative fees when a determination is made that the waiver or reduction of fees is in the public interest. Factors that may be taken into account in making such a determination include, but are not limited to:

(a) The overall costs incurred by the Board are negligible; or

(b) Providing the requested records or documents is within the normal scope of the Board's activity; or

(c) Requiring payment would cause extreme or undue financial hardship upon the requestor; or

(d) The request is a discovery request made as part of pending administrative, judicial or arbitration proceedings.

(8) If the Board denies an application for waiver or reduction of fees, the requestor may petition the Attorney General under the provisions of ORS 192.440(5) and 192.450.

(9) The Board establishes the following fees for inspection of out-of-state registrants. When an applicant for registration or renewal of registration requests an inspection, the Board shall execute an agreement with the applicant that must specify that the applicant shall pay:

(a) The travel expenses of each Board staff person (inspector) by coach-class commercial air or by rental car;

(b) The hotel costs of the inspector, subject to the applicant arranging accommodation in a hotel that is, whenever possible, on the federal per-diem list;

(c) Rental car costs for the inspector unless the applicant provides adequate ground transportation;

(d) The per-diem expenses of the inspector;

(e) A fee for the Board's time and expenses calculated as:

(A) The daily compensation of the inspector, plus the costs of any fringe benefits charged to the Board, multiplied by: one plus the number of days or partial days the inspector is away from their normal workplace; plus

(B) An administrative fee of $750.

(10) In addition to the reinspection fee specified in OAR 855-110-0007, the Board establishes the following administrative fees for a re-inspection of any Oregon drug outlet that is necessary to verify corrections of violations found on an initial inspection:

(a) The travel, hotel and per-diem costs for the inspector; and

(b) The hourly compensation of the inspector plus the cost of any fringe benefits charged to the Board multiplied by the number of hours necessary for the reinspection.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 192.430 & 192.440
Hist.: PB 10-1990, f. & cert. ef. 12-5-90; PB 1-1996, f. & cert. ef. 4-5-96; BP 2-2010, f. 2-12-10, cert. ef. 3-1-10