**DIVISION 1**

**PROCEDURAL RULES**

**855-001-0000**
**Notice of Proposed Rule**

Prior to the adoption, amendment, or repeal of any rules, except temporary rules, the State Board of Pharmacy shall:

(1) Publish notice of the adoption, amendment, or repeal in the Secretary of State's Bulletin referred to in ORS 183.360 at least fifteen (15) days prior to the effective date.

(2) Mail such notice to persons on the State Board of Pharmacy's mailing list established pursuant to ORS 183.335(6).

(3) Mail or deliver such notice to United Press International and Associated Press.

(4) With the exception of rules under section (7) of this rule, mail such notice to the following persons or organizations, where the Board's Executive Officer determines what such person or organization would be likely to have an interest in the subject matter of the proposal or would be likely to notify interested persons of the proposal:

(a) Oregon State Pharmaceutical Association and local affiliated organizations;

(b) Portland Retail Druggists Association;

(c) Professional Society of Pharmacists;

(d) Oregon Society of Hospital Pharmacists;

(e) Oregon Veterans in Pharmacy;

(f) Affected licensees of the Board.

(5) In the case of rules relating to *Aerosols and Laetrile, in addition* to mailings under section (4) of this rule, mail such notice to: United Grocers, Inc.

(6) In the case of rules relating to *DMSO, in addition* mailings under section (4) of this rule, mail such notice to:

(a) Oregon State Board of Medical Examiners;

(b) School of Medicine (University of Oregon Health Sciences Center);

(c) Oregon Medical Association;

(d) Local medical societies;

(e) Oregon Health Care Association.

(7) In the case of rules relating to *written consent for experimental drugs*, mail such notice to:

(a) Oregon State Board of Medical Examiners;

(b) School of Medicine (University of Oregon Health Sciences Center);

(c) Oregon Medical Association;

(d) Local medical societies;

(e) Oregon Health Care Association.

(8) In the case of rules relating to *controlled substances, in addition* to mailings under section (4) of this rule, mail such notice to:

(a) Oregon State Board of Medical Examiners;

(b) School of Medicine (University of Oregon Health Sciences Center);

(c) Oregon Medical Association;

(d) Local medical societies;

(e) Oregon Health Care Association;

(f) Oregon State Board or Dental Examiners;

(g) Oregon State Association of Podiatry Examiners;

(h) Oregon State Board of Veterinary Medical Examining Board Examiners;

(i) Oregon State Police;

(j) Oregon Board on Police Standards and Training;

(k) Oregon Police Chief Association;

(l) Oregon District Attorneys Association;

(m) Oregon State Bar.

Stat. Auth.: ORS 183
Stats. Implemented:
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

**855-001-0005**
**Model Rules of Procedure**

The Model Rules of Procedure as promulgated by the Attorney General of the State of Oregon under the Administrative Procedures Act effective September 9 1995, are by this reference adopted as the rules of procedure of the State Board of Pharmacy and shall be controlling except as otherwise required by statute or rule.

[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 475.035 & ORS 689.205
Stats. Implemented: ORS 689.185
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

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

In addition to the requirements stated in OAR 137-003-0001 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 consequence of failure to answer. A statement of the consequences of failure to answer may be satisfied by enclosing a copy of OAR 855-001-0015 with the notice.

Stat. Auth.: ORS 183

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

**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

**855-001-0020**
**Letters Relating to Appearances and Disciplinary Action**

All letters relating to appearances and disciplinary action will be sent by certified mail, return receipt requested.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
Hist.: 1PB 2-1981, f. & ef. 8-20-81

**855-001-0025**
**Notification of Disciplinary Action**

When disciplinary action has been taken against an Oregon licensee, including voluntary surrenders, all states licensing that pharmacist, as well as the National Association of Boards of Pharmacy, shall be notified of this action.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
Hist.: 1PB 2-1981, f. & ef. 8-20-81

**855-001-0030**
**Request for Appearance**

The Board may request a licensee to voluntarily appear before the Board prior to taking disciplinary action. The Board shall inform the licensee of the general nature of the complaint or other matters giving rise to the possible disciplinary action. The Board shall also inform the licensee:

(1) That any statement or other information provided during the appearance may be used against the licensee in a disciplinary action.

(2) That the licensee is entitled not to make any statement during the appearance that may tend to jeopardize the pharmacist's license.

(3) That the licensee may be represented by counsel.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
Hist.: 1 PB 2-1981, f. & ef. 8-20-81; PB 4-90, f. & cert. ef. 4-12-90

**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 request from the Board, subject only to the exercise of any applicable right or privilege.

Stat. Auth.: ORS 475.035, ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315
Stats. Implemented:
Hist.: PB 1-1992, f. & cert. ef. 1-31-92

## DIVISION 6

## DEFINITIONS

**855-006-0005**
**Definitions of Elements of Practice of Pharmacy**

The following terms describing the "practice of pharmacy" under ORS Chapter 689 and OAR Chapter 855 have the following meaning:

(1) "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.

(2) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (i) as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(3) "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.

(4) "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 a non-prescription drug or commercially packaged legend drug or device.

(5) 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 a 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 abuse or abuse.

(6) "Proper and safe storage of drugs and devices and maintenance of proper records therefor" 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.

(7) "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.

(8) "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.

(9) "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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.005 (30)

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

**855-006-0010**
**Miscellaneous Definitions**

As used in ORS Chapter 689 and OAR Chapter 855:

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

(2) "Unprofessional conduct" means;

(a) Repeated or gross negligence in the practice of pharmacy; or

(b) 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

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

(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 which is prohibited by state or federal law or regulation.

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

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

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

(5) "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.

(6) "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.

(7) "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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.005 (30)

Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1988, f. & cert. ef. 3-24-88; PB 5-1992, f. & cert. ef. 10-23-92; PB 1-1995, f. & cert. ef. 4-27-95; BP 4-1998, f. & cert. ef. 8-14-98; BP 1-1999(Temp), f. & cert. ef. 1-19-99 thru 7-28-99; administrative correction 8-9-99

## DIVISION 10

## BOARD ADMINISTRATION AND POLICIES

**855-010-0001**
**Definitions**

"Board" means Oregon State Board of Pharmacy.

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

**855-010-0005**
**Monthly Meetings**

(1) The Board meetings shall be held on the third Wednesday and Thursday of each month, unless otherwise 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.

Stat. Auth.: ORS 689

Stats. Implemented:

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

**855-010-0010**
**May Meetings**

(1) The annual meeting of the Board shall be held in May of each year for the election of officers and the transaction of other business. If the Board does not meet in May, the annual meeting shall be held at the next scheduled Board meeting following the month of May.

(2) The Board shall determine the content and subject matter of each examination and the place, time and date of administration of the State Board Examinations. The Board shall approve accredited schools of pharmacy annually.

Stat. Auth.: ORS 475 & 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 3-1987, f. & ef. 3-30-87

**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

## DIVISION 19

## LICENSING OF PHARMACISTS

**855-019-0005**
**Examinations, Grades Required**

(1) Applicants otherwise eligible for licensure as pharmacists by examination will be given the examination if they hold an earned degree or a certificate from an accredited school or college of pharmacy that they have completed all requirements for such degree and the degree will be conferred.

(2) The examination will be the National Association of Boards of Pharmacy Standard Examination for Licensure. A score of not less than 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination at the next scheduled testing date. The results of the NABPLEX examination, with a passing score, shall remain valid for up to one year from date of examination. The Board for good cause may extend the validity of the NABPLEX score beyond one year.

(3)(a) In addition, the Board shall administer a jurisprudence examination. This examination shall be prepared to measure the competence of the applicant regarding the statutes and rules governing the practice of pharmacy. A score of not less than 75 shall be a passing score for this examination. A candidate who does not attain this score may retake the examination at the next scheduled testing date. The results of the jurisprudence examination, with a passing score, shall remain valid for up to six months from date of examination;

(b) The jurisprudence examination will be administered at completion of internship training.

(4) An applicant who has failed the Board examination may submit an affidavit of intent to take the next regularly scheduled examination as evidence of good faith that the applicant is still pursuing a license as a pharmacist. The Board will allow the applicant licensure as an intern for that period of time. Any subsequent renewal of licensure as an intern is subject to the discretion of the Board.

(5) In order to be eligible to sit for licensure examination, applicants who are graduates of a college of pharmacy outside the United States must hold a certificate from the Foreign Pharmacy Graduate Equivalency Committee and must pass the TSE (Test of Spoken English) with a score of not less than 50.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.255(2)(b)
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

**855-019-0007**
**Schedule of Examinations**

(1) The licensing examinations required in OAR 855-019-0005 will be given at least twice a year.

(2) Reciprocity jurisprudence exams will be offered at least four times a year.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
Hist.: 1PB 2-1981, f. & ef. 8-20-81; 1PB 2-1984, f. & ef. 3-7-84; 1PB 3-1985, f. & ef. 12-2-85

**855-019-0010**
**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, except the instructions given at the time of examination. 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. No state Board examinations shall be given in any subject or subjects unless authorized by the Board.

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

**855-019-0015**
**General Reciprocity Requirements**

(1) Applicants for a pharmacist's license by reciprocity must be qualified under ORS 689.265 and these rules.

(2) The applicant otherwise eligible must pass an examination given by the Oregon Board covering jurisprudence with a grade of 75 or more. The results of the jurisprudence examination, with a passing score, shall remain valid for up to six months from date of examination.

(3) The applicant must be registered by written examination in the state on which the applicant bases the reciprocity application and must be in good standing in that state.

(4) No reciprocity will be granted unless the applicant appears in person before the Board or the Board's designated representative.

(5) The applicant:

(a) Must have engaged in the practice of pharmacy for period of at least one year; or

(b) Have met the internship requirements of this state within the one-year period immediately previous to the date of such application. Engaged in the practice of pharmacy for one year shall mean licensed as a pharmacist for one year or more and validation of 1,500 hours of work experience as a licensed pharmacist. Validation of hours shall be made at time of application.

(c) The original application for transfer of pharmaceutic licensure, photocopy of birth certificate, and letter of intent to take the law exam must be submitted to the Board in person or by mail with a postmark showing a date on or before the first day of the month of the desired law exam date.

(6) 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 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

**855-019-0020**
**Fees, Reciprocity**

The Oregon state fee for a pharmacist's license by reciprocity is set by Division 110 of this chapter.

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

**855-019-0025**
**Grades Required, Reciprocity**

The applicant for pharmacist's license by reciprocity must have had examination grades at the time of initial license or registration consistent with the following:

(1) If initially registered or licensed between December 13, 1904, and June, 1936, grades must not be less than 60 percent in any subject and a general average of not less than 75 percent.

(2) If initially registered or licensed in June, 1936, and thereafter, grade in practical work must not be less than 75 percent.

(3) All reciprocities graded under NABPLEX examination shall have raw score equivalent to Oregon State Board NABPLEX examination.

(4) After May 1, 1980, the candidate must have passed the NABPLEX or equivalent examination.

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

**855-019-0030**
**Educational Requirements, Reciprocity**

The applicant for pharmacist's license for reciprocity must have had education at the time of initial license or registration consistent with the following:

(1) If initially registered or licensed from January 1, 1921, to January 1, 1922, the applicant must have attended at least one year at a college of pharmacy.

(2) If initially registered or licensed from January 1, 1922 to July , 1925, the applicant must have attended and completed at least a two-year pharmacy course. The last degree for completion of the two-year course was granted in June, 1925, and the last group of applicants coming under this classification examined then.

(3) If initially registered or licensed from July 1, 1925, to July 1, 1933, the applicant must be a graduate of at least a three-year pharmacy course. The last three-year degree in Oregon was granted in June, 1933, and the last group of three-year graduates examined then. Applicants who entered college since July, 1930, must be graduates of a four-year pharmacy course.

(4) All applicants for reciprocal registration who are registered or licensed as pharmacists in their respective states on and after July 1, 1944, shall be required to be graduates of schools or colleges of pharmacy accredited by the Oregon Board of Pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.265
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

**855-019-0035**
**Employment of Out-of-State Pharmacists**

Before an out-of-state pharmacist is employed as a pharmacist in an Oregon registered pharmacy, the employer shall check with the Board to determine the Oregon licensure status of the out-of-state pharmacist. If the person is not licensed in Oregon, the person shall not be employed as a pharmacist.

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

**855-019-0040**
**Renewal of Licenses**

If the pharmacist annual license fee is not paid by June 30 of the current year, the license of the delinquent pharmacist shall be removed from the Board's active file:

(1) Reinstatement of the pharmacist's license shall be as follows:

(a) Payment of the annual license fees for all years during which the license has been lapsed and for the current year and the delinquent fees for those years; and

(b) Certification of the continuing education requirement for all years in which the license has lapsed.

(2) Pharmacists in good standing who have retired from the practice of pharmacy after having been licensed 20 years shall pay only the annual license fees for the year in which they seek a license but shall be subject to the requirement of certification of continuing education. The references to lapsed time shall be deemed a reference to time since retirement. Those pharmacists who retired prior to April 3, 1980, will follow the requirements of the rules pertaining at that time.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
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

**855-019-0050**
**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 shall consist of a showing by the petitioner of changed circumstances from those surrounding the revocation, suspension or restriction of license. The presentation shall 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 cause 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 shall be in writing and shall 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 shall include a recitation of the treatment, programs, or other endeavors or activities under-taken 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
Stats. Implemented:
Hist.: 1PB 1-1982, f. & ef. 3-8-82

**855-019-0055**
**Grounds for Discipline**

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

(a) Unprofessional conduct;

(b) Repeated or gross negligence;

(c) Incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, competence and safety to the public;

(d) Habitual or excess use of intoxicants, drugs or controlled substances;

(e) 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;

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

(g) 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;

(h) 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;

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

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

(k) Being found by the Board to be in 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.

(2) "Unprofessional conduct" means:

(a) Repeated or gross negligence in the practice of pharmacy; or

(b) 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, manufacturers or distributors of drugs, medications or devices;

(E) Health care facilities;

(F) Government agencies;

(G) Drug outlets.

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

(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 which is prohibited by state or federal law or regulation;

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

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 1-1989, f. & cert. ef. 1-3-89

## DIVISION 21

## CONTINUING PHARMACY EDUCATION

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

(1) Commencing with the licensing period beginning July 1, 1977, and for licensing periods thereafter, no pharmacist license renewal will be issued by the Board of Pharmacy unless the applicant, in the 12 months preceding the renewal application, has satisfactorily completed 1-1/2 continuing pharmacy education units (15 hours) in an approved continuing pharmacy education program or programs approved by the Board or unless he has passed an examination given by the Board as provided for in these rules.

(2) Section (1) of this rule 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
Stats. Implemented:
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

**855-021-0010**
**Continuing Pharmacy Education Programs**

(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 and such other methods approved by the Board:

(a) A program shall consist of pharmaceutical post-graduate education in the general area of:

(A) Therapeutics, pharmacy and drug law, and legal aspects of health care. Therapeutics is defined as the properties and actions and treatment of the disease state. At least eleven of the required 15 hours of continuing education credits must be earned in the area of therapeutics, pharmacy and drug law, and legal aspects of health care. At least one of the eleven hours must be earned in the area of pharmacy and drug law;

(B) Administrative and socio-economic aspects of health care. Four of the required 15 hours of continuing education credits may be earned in this area.

(b) Programs shall provide for examinations or other methods 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 clock hours offered;

(e) Total number of clock hours in therapeutics, pharmacy and drug law, and legal 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) Providers shall submit provider applications to the Board in duplicate within 30 days of the date of program, and provide attendees with proof of attendance, which must show hours provided in each of the following: therapeutics, pharmacy and drug law, and administrative and socio-economic aspects of health care. Providers must maintain attendance lists for three years.

(4) Ten clock hours of education or preparation and presentation in an approved continuing pharmacy education program or programs constitutes one continuing pharmacy education unit. One clock hour shall consist of at least 50 minutes.

(5) Continuing pharmacy education credit accumulated in excess of the required 1.5 continuing pharmacy education units (15 hours) for annual license renewal cannot be carried forward and applied to succeeding license renewal periods, except that excess credit accumulated within 30 days prior to license renewal may be carried forward to the next license renewal period.

(6) 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.

(7) A maximum of ten 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 clock 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.

(8) 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.

(9) The Board recommends but does not require that at least five hours of CE credit be obtained in a group setting of at least five pharmacists. Correspondence courses with provider evaluation and certification of completion may be approved, however, self-study courses with self-evaluation will not be approved.

(10) Highly specialized courses shall be reviewed and approved on an individual basis.

Stat. Auth.: ORS 435, ORS 475, ORS 689.155 & ORS 689.205
Stats. Implemented:
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

**855-021-0015**
**Continuing Pharmacy Education Program Lists**

(1) The Board will maintain a list of current Board-approved continuing pharmacy education programs and will distribute the list to licensed pharmacists upon individual request. The list will include the subject matter, type of program, the provider or sponsor, the date and location if known, and the number of continuing pharmacy education units approved for credit.

(2) Pharmacists participating in programs that are not within the list of approved programs act at the risk that the program will not receive subsequent approval of the Board and thus risk disallowance of credit.

Stat. Auth.: ORS 689
Stats. Implemented:
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

**855-021-0025**
**Continuing Pharmacy Education — Reciprocity**

The Board recognizes reciprocal licensing of only pharmacists who are licensed in good standing in some other state at the time of application to the Board and at the time of issuance of the Oregon license. 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:
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

**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.

(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, ORS 475 & ORS 689
Stats. Implemented:
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

**855-021-0035**
**Continuing Education (Examination)**

(1) Any applicant for license renewal may, in lieu of completing the required continuing pharmacy education units, satisfactorily pass a continuing education examination given by the Board no later than eight months prior to the next date for renewal of the annual license. If the applicant passes the open book examination with a score of not less than 90 percent, the Board will certify the applicant as having met the continuing pharmacy education requirement for license renewal.

(2) The Board will provide and administer the examination. A fee for the examination is not required. The board will give special consideration to develop an examination that meets the intent and purpose of ORS 689.285.

Stat. Auth.: ORS 689.205 & ORS 689.285
Stats. Implemented: ORS 689.285(4)(a)
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; PB 4-1992, f. & cert. ef. 8-25-92; PB 3-1994, f. & cert. ef. 7-1-94; PB 1-1996, f. & cert. ef. 4-5-96

**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 June 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
Stats. Implemented:
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

**855-021-0050**
**Renewal Application**

(1) The annual renewal notice shall be returned to the Board with the appropriate fee and with certification of satisfactory completion of continuing pharmacy education requirements signed by the licensee. The completed form shall identify the approved continuing education program or programs completed, date completed, and location. The form will be filed in the licensee's continuing pharmacy education file. Incomplete renewal applications will not be processed, and will be returned to the applicant with an explanatory note.

(2) The Board may randomly select submitted renewal notice forms for audit and verification of contents.

Stat. Auth.: ORS 689
Stats. Implemented:

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

**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 & ORS 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 31

## INTERNSHIP REGULATIONS

**855-031-0005**
**Definitions**

(1) A "pharmacy intern" means any person who has completed the first professional year, normally the junior or third academic year of a course of study at an approved college of pharmacy, is a student in good academic standing at an approved college of pharmacy, or is a graduate of an approved college of pharmacy, or holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee, and is licensed with the Board as an intern.

(2) A "preceptor" means a pharmacist licensed and in good standing, registered as a preceptor by the Board to supervise the internship training of an intern.

(3) "Internship" means a professional and practical experience program approved by the Board.

(a) "Pharmacy Practice Internship" means experience toward achieving competency in the practice of pharmacy in a registered pharmacy pursuant to ORS 689.245, at a site licensed or approved by the Board and for which no academic credit is granted to the intern;

(b) "Externship" means experience toward achieving competency in the practice of pharmacy in a specialized patient-care program, developed and administered by a school or college of pharmacy and which is approved by the Board. The school or college may grant academic credit for this experience;

(c) "Clerkship" means experience toward achieving competency in specialty practices of pharmacy in programs developed and administered by a school or college of pharmacy and which must be approved by the Board before the course is offered if internship hours are to be submitted by the intern;

(d) "Other Internship" means experience toward achieving competency in the practice of pharmacy in a program approved in advance by the Board.

(4) "Competency Checklist" means a descriptive listing of those specific professional and practical activities approved by the Board and deemed necessary to have successfully completed prior to licensure as an Oregon pharmacist.

(5) "Basic Internship Competencies" means those internship competencies achieved and documented by the preceptor after completion of the intern's first professional year.

(6) "Intermediate Internship Competencies" means those internship competencies achieved and document's second professional year.

(7) "Advanced Internship Competencies" means those internship competencies achieved and documented by the preceptor during and/or after completion of the intern's third professional year.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 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

**855-031-0010**
**Application — Forms — Fees — Intern License — Preceptor Registration**

(1) Applications for licensure and renewal as a pharmacy intern, registration and renewal as a pharmacy preceptor, and copies of the current **Internship Manual** may be obtained from the Board Office.

(2) The initial license for a qualified pharmacy intern shall be issued by the Board after the receipt of a completed application and payment of the fee prescribed in Division 110 of this Chapter. Licensure shall be deemed registration under ORS 689.005 (16).

(3) A pharmacy intern license is valid for up to three years.

(4) Pharmacy interns are required to notify the Board in writing within 15 days of beginning or changing an internship site.

(5) Pharmacy interns are required to notify the Board in writing within 15 days of a change in permanent residence.

(6) The pharmacy intern license must be conspicuously displayed in the internship site at all times.

(7) The registration of a qualified pharmacy preceptor shall be issued by the Board upon receipt of a completed application. Registration of preceptors is required under ORS 689.005(27).

(8) A pharmacy preceptor registration is valid for up to three years.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented:
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

**855-031-0015**
**Approved Internship Experience Areas**

(1) Internship shall be acquired in any one or a combination of the following approved internship experience areas:

(a) Pharmacy Practice Internship;

(b) Externship;

(c) Clerkship;

(d) Other Internship.

(2) In order for eligible pharmacy students to receive intern hours for externship and clerkship experiences, the College of Pharmacy must submit the syllabuses to the Board for approval before offering the course:

(a) The syllabus must show which of the competencies from the Competency Checklist will be included in the externship or clerkship experience;

(b) For purposes of obtaining intern hours from the externship or clerkship experience, the student shall be responsible for licensing as an intern with the Board and maintaining the required Competency Checklist and Experience Affidavit/Hours Logs;

(c) The student's preceptor in the externship and clerkship courses shall also fulfill the responsibilities listed in OAR 855-031-0045.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented:
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

**855-031-0020**
**Internship Requirements**

(1) Internship shall consist of not less than 2,000 Board approved hours.

(2) Not more than 48 hours per week may be credited toward the internship requirement.

(3) Interns are required to complete the Board's Competency Checklist with their preceptor(s).

(4) Internship requirements in this section shall apply to all interns who are initially licensed in March 1994 or later.

Stat. Auth.: ORS 689.155 & ORS 689.205
Stats. Implemented:
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

**855-031-0030**
**Out-of-State Internship Experience**

In order to obtain credit for internship experience outside the State of Oregon, pharmacy interns must be licensed in the state in which they practiced and meet or exceed the minimum intern requirements of the Oregon State Board. The location and type of experience, the preceptor, and the completed Oregon Competency Checklist shall be certified to the Oregon Board of Pharmacy by the Board of Pharmacy or other authorized certifying representative of that state.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented:
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

**855-031-0033**
**Internship Experience in Federal Facilities**

In order to obtain internship experience in a federal facility located in Oregon, an intern must be registered with the Oregon Board of Pharmacy. 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 registered as a preceptor with the Oregon Board of Pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.255
Hist.: PB 1-1996, f. & cert. ef. 4-5-96

**855-031-0035**
**Eligibility for Internship Experience**

Pharmacy interns shall not be eligible for internship experience unless they are pursuing a degree in good faith and are in good academic standing at an approved college of pharmacy, or such a degree is conferred by the school or college of pharmacy, that qualifies them for licensure as a pharmacist. Eligibility for internship experience when an applicant has failed the Board examination is described in OAR 855-019-0005(4). 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.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
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 7-1990, f. & cert. ef. 12-5-90

**855-031-0040**
**Internship Reports**

(1) Interns are required to submit their Competency Checklist in three parts, upon fully completing each part:

(a) Part 1 — Basic Internship Competencies;

(b) Part 2 — Intermediate Internship Competencies;

(c) Part 3 — Advanced Internship Competencies.

(2) The applicable Experience Affidavit/Hours Log(s) shall accompany each individual part of the Competency Checklist.

(3) Each part of the Intern Competency Checklist and all Experience Affidavit/Hours Logs shall be notarized.

(4) Final reports and written intent to take the law exam must be submitted to the Board in person or by fax by the first day of the month of the desired law exam date, or by mail with a postmark showing a date on or before the first of the month.

(5) The Intern Experience Affidavits/Hours Log shall list the actual number of hours and the dates covered by those hours.

(6) Approval of internship experience reports shall be given by the Board when the reports are completed and indicate that significant progress in internship experience toward achieving competency in the practice of pharmacy has been made.

(7) The internship experience reports shall be signed by the pharmacy intern and the preceptor(s).

(8) The intern may report to the Board voluntarily the preceptor's aptitude and willingness to perform the duties of a preceptor, or shall do so upon request by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 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

**855-031-0045**
**Preceptor — Responsibilities**

(1) A registered preceptor shall have been an actively practicing pharmacist for at least one year immediately prior to supervising a pharmacy intern.

(2) The preceptor may report to the Board voluntarily, the progress and aptitude of a pharmacy intern under the preceptor's supervision, or shall do so upon request by the Board.

(3) The preceptor shall provide the pharmacy intern with internship experience which in the preceptor's judgment will increase the intern's competency in the practice of pharmacy.

(4) The preceptor shall be responsible for supervision of the majority of the pharmacy intern's hours and shall designate on the Internship Experience Affidavit/Hours Log the pharmacists who acted as supervisor during the preceptor's absence.

(5) The preceptor shall certify the Internship Experience Affidavit/Hours Log. A separate Affidavit must be filed when the intern changes preceptors.

(6) A pharmacist may not supervise more than one pharmacy practice intern simultaneously.

(7) The preceptor shall assure that the intern is currently licensed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 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

**855-031-0050**
**Completion of the Internship Experience Requirement**

(1) Upon completion of internship experience requirements, an applicant for licensure as a pharmacist in Oregon shall file internship reports as required under OAR 855-031-0040 for the Board's approval.

(2) The Board shall notify applicants of their eligibility to take the law examination as described under OAR 855-019-0005(3).

Stat. Auth.: ORS 475.035 & ORS 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 7-1990, f. & cert. ef. 12-5-90; PB 1-1994, f. & cert. ef. 2-2-94

**855-031-0055**
**Pharmacist Licensure — Payment of Fees**

Upon meeting of all requirements for licensure, a pharmacy intern shall, before practicing pharmacy in this state, complete an application for licensure, pay the annual license fee as prescribed in Division 110 of OAR Chapter 855, and obtain a license which shall expire on June 30 following the date of issue.

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; PB 5-1990, f. & cert. ef. 4-12-90; PB 7-1990, f. & cert. ef. 12-5-90

## DIVISION 35

## OPERATION OF NONPRESCRIPTION AND MEDICINAL GAS DRUG 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.

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.

(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.

Stat. Auth.: ORS 689.155 & ORS 689.205
Stats. Implemented: ORS 475.035, ORS 689.135 & ORS 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

**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 & ORS 689.205
Stats. Implemented: ORS 689.305, ORS 689.315 & ORS 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 & ORS 689.205
Stats. Implemented: ORS 689.305 & ORS 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 & ORS 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 non-prescription drugs in the original and unbroken packages only, properly labeled according to state and federal law, in conformity with rules of the Board. No nonprescription drug outlet shall purchase or receive nonprescription drugs from a source not registered with the Board.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented: ORS 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

**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, ORS 689.155, ORS 689.205, ORS 689.305 & ORS 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 & ORS 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**
**Medicinal Gas Drug Outlet (Class C)**

(1) Medicinal Gas Drug Outlets shall distribute medicinal Oxygen only on the order of a practitioner.

(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 medicinal gas shall be maintained for a minimum of three years and shall be readily retrievable.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented: ORS 689.305 & ORS 689.325

Hist.: PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96

## 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 & ORS 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

### 855-041-0010
### 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 & ORS 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 & ORS 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, ORS 689.155, ORS 689.205, ORS 689.305 & ORS 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) Pharmacist-in-Charge:

(a) Each pharmacy shall 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;

(b) A change of the pharmacist-in-charge shall be filed with the Board within 15 days of its occurrence on an application form provided by the board. An inventory of all controlled substances shall be taken within 10 days of the effective date of change, shall be dated and signed by the new pharmacist-in-charge and shall be maintained in the pharmacy with other controlled substances records for three years;

(c) The pharmacist-in-charge, along with other licensed pharmacy personnel involved with management of the pharmacy, shall 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 conformance with the keeping and inventory requirements of federal law and board rules;

(d) The pharmacist-in-charge of any pharmacy where discrepancies are noted upon inspection by the board or its staff shall, within 30 days of receiving notice of such discrepancy, submit in writing to the board the steps taken or proposed to eliminate the discrepancy. Failure to submit such report and to eliminate discrepancy shall be grounds for disciplinary action by the Board;

(e) No pharmacist shall be designated pharmacist-in-charge of more than one pharmacy, however this requirement may be waived in the case of a pharmacist serving a facility with both a retail and institutional drug outlet registration or in the case of a pharmacist serving an institutional pharmacy on a part-time basis;

(f) The pharmacist-in-charge shall conduct, on an inspection form provided by the Board, an annual inspection of the pharmacy by February 1. The completed report form shall be filed in the pharmacy and be available to the Board for inspection and be kept on file for three years;

(g) The pharmacist-in-charge shall verify, on employment and annually, the licensure of pharmacists under their supervision.

(2) Pharmacists:

(a) All pharmacists while on duty, shall be responsible for complying with all state and federal laws and rules governing the practice of pharmacy;

(b) All pharmacists and pharmacist-interns shall notify the Board of Pharmacy in writing of any change in employment location or change of residence address within 15 days.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented: ORS 689.155 & ORS 689.315
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

**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 & ORS 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, ORS 689.155, ORS 689.205, ORS 689.305 & ORS 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, ORS 689.155, ORS 689.205, ORS 689.305 & ORS 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 one pharmaceutical reference with current, properly filed supplements and/or updates from the following list:

(a) United States Pharmacopeia Dispensing Information;

(b) Facts and Comparisons;

(c) American Hospital Formulary.

(2) Current and properly filed ORS Chapters 475 and 689; current and properly filed OAR Chapter 855; and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in a looseleaf binder or other readily retrievable means.

(3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.

(4) A prescription balance able to weigh substances to a degree of accuracy necessary to and consistent with the needs of the practice.

(5) Measuring devices capable of accurately measuring volumes from 1 ml. to 500 ml.

(6) Funnel.

(7) Stirring rod.

(8) Suitable refrigeration.

(9) Mortar and pestle.

(10) Sink with running hot and cold water.

(11) Exceptions to the above list may be approved by the Board of Pharmacy.

Stat. Auth.: ORS 475.035 & ORS 689.205
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; 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

**855-041-0050**
**Applicability of Rules**

The provisions of OAR 855-041-0005 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 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 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89

**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: The publication(s) referred to or incorporated by reference in this rule 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 Files**

"Filing" shall mean the storage of the information on the prescription in such a manner that this information is safeguarded and readily retrievable. Every pharmacy and pharmacist-in-charge of a pharmacy is responsible for and shall keep in the pharmacy a book or file of original prescriptions as evidence of compliance with this rule. All prescriptions received from a duly licensed medical practitioner and compounded or dispensed at such pharmacy or drug store shall be numbered, dated and filed in the order in which they were compounded or dispensed and shall be produced in court or before any grand jury whenever lawfully required to do so. Such book or file of original prescriptions shall at all times be open for inspection by the prescriber, the Board of Pharmacy or its duly authorized agent, and this record shall be preserved for a period of not less than three years.

Stat. Auth.: ORS 475.035 & ORS 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

**855-041-0063**
**Sterile Parenteral Products**

(1) The following rules apply to all pharmacies compounding sterile parenteral products. Pharmacies and pharmacists dispensing sterile parenteral products with expiration times of 48 hours or less shall comply with all of these rules except section (10) of this rule. Section (10) of this rule applies only to those pharmacies or pharmacists dispensing sterile parenteral products with expiration times greater than 48 hours.

(2) Pharmacist-in-Charge: The pharmacist-in-charge shall be responsible for the preparation of parenteral products compounded within the pharmacy and shall:

(a) Be responsible to ensure all pharmacy personnel involved in preparing parenteral products have training and demonstrated competence in the safe handling and compounding of parenteral products;

(b) Establish a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities;

(c) Establish a procedure for verification by the pharmacist of the preparation of each completed parental product. This verification shall be accomplished by reviewing that:

(A) The drug and dose ordered are appropriate for the patient;

(B) The correct drug and solution were selected;

(C) The label is correct and complete;

(D) The calculation of the amount transferred is correct.

(d) Documentation of the verification shall be done by hand written initials of the pharmacist responsible for the review;

(e) Develop and maintain written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products.

(3) Work Area and Equipment:

(a) The pharmacy shall have a specified area for the preparation of parenteral products which shall provide space for compounding, labeling, and sterile preparation of the medication;

(b) The area shall be designated to avoid outside traffic and air flow;

(c) The area shall have clean surfaces, walls and floors;

(d) A sink shall be located in the area for cleaning supplies and equipment, and for handwashing by personnel;

(e) The area shall not be used for storage of supplies and materials in excess of what is required to prepare parenteral products.

(4) Storage:

(a) The room temperature of the storage space for all raw materials shall be adequately controlled and maintained between 15–30°C.;

(b) There shall be a refrigerator of sufficient capacity to meet the storage requirements of all material requiring refrigeration. Refrigerator temperature shall be in the range of 2–8°C.;

(c) There shall be a freezer of sufficient capacity to meet storage requirements if products are to be frozen (e.g., reconstituted antibiotics). Temperatures shall be below -10°C., and there shall be a means to determine if freezing has been interrupted.

(5) Labeling: In addition to regular labeling requirements, the label shall include:

(a) Rate of infusion, as appropriate;

(b) Expiration date;

(c) Storage requirements or special conditions, if applicable;

(d) Name and concentration of all ingredients contained in the parenteral products, including primary solution;

(e) Hand written initial of the pharmacist certifying for accuracy.

(6) Patient Care Services: Consultation shall be available to the patient and/or primary caregiver concerning proper use of parenterals and related supplies furnished by the pharmacy.

(7) Cytotoxic Medications: Any pharmacy providing cytotoxic medications shall establish procedures for their preparation, storage, administration, cleanup and disposal in accordance with current Occupational Safety and Health Administration (OSHA) guidelines.

(8) Reference Requirements: In addition to requirements set forth in OAR 855-041-0040, current copies of the following shall be maintained by all pharmacies involved in the preparation of parenteral products:

(a) **American Hospital Formulary Service, Drug Information** with current supplements or comparable reference approved by the Board;

(b) **Trissel's Handbook of Injectable Drugs** or comparable reference approved by the Board.

(9) Policies and Procedures: Written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products is required and shall be available for inspection at the pharmacy. Written policies and procedures shall include, but not be limited to:

(a) Compounding, labeling and storage of parenteral products;

(b) Administration of intravenous therapy;

(c) Storage and maintenance of equipment and supplies;

(d) Training of personnel, patient and caregiver;

(e) Procedures for handling cytotoxic agents;

(f) Quality assurance programs;

(g) Recordkeeping requirements;

(h) Procedures for cleaning the compounding area.

(10) Pharmacies dispensing parenteral products with expiration times greater than 48 hours shall comply with all of these rules and shall in addition:

(a) Have a certified and inspected laminar air flow hood or positive air flow room for the preparation of parenteral products which is certified and inspected annually. The preparation area shall be ventilated in such a manner as to not interfere with laminar flow hood conditions. Documentation of proper hood maintenance including HEPA filter inspection, prefilter maintenance, dis-

infecting, and cleaning shall be kept in the pharmacy for a three year period;

(b) Compound all parenteral products dispensed in quantities with expiration times greater than 48 hours in a laminar air flow hood or in a positive air flow room;

(c) Establish procedures for monitoring microbial growth;

(d) Establish procedures for testing the aseptic techniques of personnel and documentation thereof.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 689

Stats. Implemented:

Hist.: PB 5-1987, f. & ef. 5-1-87; PB 12-1989, f. & cert. ef. 8-11-89

**855-041-0065**

**Requirements for Prescriptions — Prescription Refills**

Prescriptions and prescription refills shall be dispensed only in accordance with the prescriber's authorization upon the request of the patient. When a prescription is transmitted orally, both the receiving pharmacist's name or initials and the name of the person transmitting shall be noted on the prescription.

(1) Every original prescription received shall contain:

(a) The date when the prescription was received;

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

(c) 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 855-080-0085;

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

(e) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(f) The directions for use, if given by the practitioner;

(g) The date of filling, the hand written signature or hand written initials of the dispensing pharmacist, or intern and supervising pharmacist, and the total number of refills authorized by the prescribing practitioner. Controlled substances prescriptions in Schedule II shall be canceled by the pharmacist writing his signature on the face of the prescription; and

(h) One of the following phrases or notations, in the 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 the name of the person transmitting the authorization shall be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III, IV, and V 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 judgement 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) The pharmacist shall write the date and his signature or initials on the original prescription at the time of refills thereof and if a quantity is dispensed other than the face amount on the original prescription, the entry shall also include the quantity dispensed.

(5) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber. 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) As an alternative to the procedures provided above on refills, a patient profile system may be used for the storage and retrieval of refill information for all prescription orders subject to compliance with the following conditions:

(a) Any such medication record system must provide original prescription order information which shall include, but is not limited to, data such as original prescription number, the practitioner's name, date of issuance of original prescription ordered by the practitioner, name, strength, dosage form of the substance, quantity prescribed and if different from the quantity prescribed, quantity dispensed; the directions for use; and the total number of refills authorized by the prescriber;

(b) The original prescription order shall be filed pursuant to OAR 855-041-0060;

(c) Refills shall be recorded on the medical record system to show the date of refill, pharmacist's initials and quantity dispensed if different from original quantity. Where refill authority is given other than by the original prescription, a notation that such authorization was given, the date of authorization, and the name of the person transmitting the authorization shall be recorded. This documentation must be readily retrievable;

(d) If a quantity on a refill dispensed is other than the original amount, the refill entry shall also include the quantity dispensed; and

(e) A person who is not a pharmacist or pharmacist-intern may transcribe or enter information into the medication record system. Certification of the accuracy of the transcribed prescription to the medication record shall be done by handwritten signature or initials of the pharmacist so certifying.

(7) Prescriptions shall 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 January 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.

(8) 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 cor-

rected 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

**855-041-0070**
**Computerized Pharmacy Regulations**

As an alternative to the procedures provided by OAR 855-041-0065, on refills, an automated data processing system may be used for the storage and retrieval of refill information for all prescription orders subject to compliance with the following conditions:

(1) Any such computerized systems must provide on-line retrieval (via CRT display or printout) of original prescription order information and the original prescription order shall be filed pursuant to OAR 855-041-0060.

(2) Any such computerized system must also provide, as a minimum, retrieval (via CRT display or printout) of the refill history for all prescription orders which have been refilled in the last three years. The retrievable refill history for each refill shall include, but is not limited to, the date of each refill; the original prescription number; the name, strength and dosage form of the substance and if different from the quantity prescribed, the quantity dispensed; the name or initials of the responsible pharmacist for each refill; and the total number of refills dispensed to date for the prescription order.

(3) The pharmacy shall maintain a log book or file, in which each individual pharmacist/involved in dispensing shall enter the date, the original prescription number and his initials for each refill dispensed by him. The log book or file shall provide a means of identifying the initials of those pharmacists making entries in the log book or file. The log book or file must be maintained at the pharmacy using such a system for a period of three years from the dispensing date.

(4) Any such computerized system shall have the capability of producing, within at least 48 hours, a printout of any refill data which the user pharmacy is responsible for maintaining on the computer. For example, this would include a refill-by-refill printout for any specified strength and dosage form of any substance (by either brand or generic name or both), such a refill-by-refill printout to indicate the name of the prescribing practitioner, name of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or initials of the responsible pharmacist and the number of the original prescription order. A separate daily or monthly printout of all Schedules III, IV, and V controlled substances prescriptions filled for the period shall be run and maintained separately from non-controlled prescriptions at the pharmacy for a period of three years.

(5) The pharmacy must have, except as further provided in this section, an auxiliary recording procedure which will be used for documentation of refills or prescription orders in the event that a pharmacy that employs such a computerized system experiences system down-time. This auxiliary procedure must provide information as to whether refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and must further provide that all of the appropriate refill data is retained for on-line data entry as soon as the computer system is available for use again. If such an auxiliary procedure is not maintained during down-time, refills shall not be made unless a new prescription order is obtained from the prescribing practitioner and processed as a new prescription. When this automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system within 96 hours. However, nothing in this section shall preclude the pharmacist from using his professional judgment for the benefit of a patient's health and safety.

(6) The regulations for computers do not prohibit the use of an automated data processing system solely for the purpose of a patient profile system where all storage and retrieval of refill information is maintained as stated in OAR 855-041-0065.

(7) When electronic data processing equipment is employed by any pharmacy, input of prescription information may be performed by a practitioner or a pharmacist. If orders are entered by other personnel, the pharmacist must certify the accuracy of the information entered by hand initialing and verifying the prescription order prior to the dispensing of the medication. The identity of the pharmacist verifying the order must be retained in the record.

(8) Initialing of prescription refills shall be satisfied in computerized systems by the pertinent data being retrievable.

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 2-1990, f. & cert. ef. 2-9-90

**855-041-0075**
**Transfer of Prescription Information Between Pharmacies**

(1) Prescriptions may be transferred by pharmacists between pharmacies for the purpose of refill dispensing provided that:

(a) The transferrer pharmacist invalidates the prescription on file as of the date the copy is given by writing "Void" on its face; and records on the invalidated prescription order that a copy has been issued, to whom, the date of issuance of such copy and the initials of the pharmacist issuing the transferred prescription order; and

(b) The transferee pharmacist, upon receiving such prescription directly from another pharmacist, records the following:

(A) The name and original prescription number of the pharmacy from which the prescription was transferred.

(B) The name of the transferrer pharmacist.

(C) All information constituting a prescription order including the following:

(i) Date of issuance of original prescription;

(ii) Date of last refill;

(iii) Number of valid refills remaining; and

(iv) The transferee pharmacist informs the patient that the original prescription has been canceled at the pharmacy from which it was obtained.

(2) Controlled substance prescriptions may only be transferred one time.

(3) Computerized systems or patient profile systems must satisfy all requirements of section (1) of this rule, including invalidation of the original prescription when transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership. Except when required by federal law, this requirement is met by having computer records show that a copy was given, date, by whom and to whom.

(4) Presentation of a written prescription copy or prescription label shall be for information purposes only and has no legal status as a valid prescription order. The recipient pharmacist of such copy or prescription label shall contact the prescribing practitioner for authorization to dispense the prescription, which is the same as obtaining an original prescription order.

(5) Common Electronic Files:

(a) Two or more pharmacies may establish and use a common shared electronic prescription file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.

(b) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.175
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

**855-041-0080**

**Returned Drugs and Devices**

(1) Pharmacists shall not accept the return of a controlled substance except as provided in OAR 855-080-0105.

(2) Pharmacists shall not accept the return of drugs or devices as defined by ORS 689.005 from any person once the drugs or devices have been removed from the pharmacy except as provided in section (3) of this rule.

(3) Drugs or devices previously dispensed or distributed by a pharmacist may be returned to and redispensed or redistributed by the pharmacist 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.

Stat. Auth.: ORS 475 & ORS 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

**855-041-0085**
**Duties of the Pharmacist Receiving an Oral Prescription**

Upon receipt of an oral prescription, the pharmacist filling the oral prescription shall promptly reduce the oral prescription to writing by recording:

(1) The date when the oral prescription was received.

(2) The name of the patient for whom, or the owner of the animal for which, the drug is dispensed.

(3) 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 OAR 855-080-0085.

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

(5) The name, strength, dosage form of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed.

(6) The direction for use.

(7) The date of filling, the written signature or initials of the dispensing pharmacist or intern and the total number of refills authorized by the prescribing practitioner.

(8) The written signature or initials of the receiving pharmacist and the identity of the person transmitting the prescription.

(9) The oral prescription reduced to writing shall be retained on file as required under OAR 855-041-0060, and in the case of controlled sub-stances, rules adopted by reference under Division 80 of this Chapter.

Stat. Auth.: ORS 475.035 & ORS 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

**855-041-0086**
**Verification of Prescription Authenticity**

(1) 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.

(2) A pharmacist may refuse to dispense controlled substances prescription to any person who lacks proper identification.

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

**855-041-0090**
**Optometric Diagnostic Agents**

(1) Any registered pharmacy, drug manufacturer, or wholesaler may sell or otherwise distribute diagnostic, topical pharmaceutical agents designated by the rule of the Oregon Board of Optometry, to licensed optometrists qualified to employ the use of such diagnostic agents under ORS Chapter 683.

(2) The pharmacy, drug manufacturer, or wholesaler may act under section (1) of this rule only after determining that the optometrist is qualified to employ the use of the diagnostic agents under ORS Chapter 683.

(3) Section (1) of this rule does not authorize the pharmacy to sell or otherwise distribute any of the designated agents to a patient on the prescription of an optometrist.

(4) The following diagnostic pharmaceutical agents are those authorized for sale to licensed optometrists:

(a) Anesthetics:

(A) Benoxinate 0.4%;

(B) Proparacaine HC1 0.5%.

(b) Cycloplegics/Mydriatics:

(A) Cyclopentolate, not to exceed 1%;

(B) Hydroxyamphetamine HBr 1%; Tropicamide, not to exceed 1%;

(C) Phenylephrine HC1, not to exceed 10%.

(c) Dyes: Fluorescein Na impregnated paper strips, as commonly used in the practice of optometry for some time; not to be stored in liquid form: Rose bengal 1%;

(d) Miotics (*for emergency use only*): Pilocarpine, not to exceed 4%.

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

**855-041-0095**
**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

**855-041-0100**
**Pharmaceutical Care**

(1) Patient Counseling and Monitoring:

(a) Prior to dispensing all new prescriptions, the pharmacist or pharmacist intern shall review the patient's record, and initiate and provide oral counseling to the patient or to the patient's agent or caregiver in all ambulatory care settings and for discharge medications in hospitals unless:

(A) Counseling is refused; or

(B) Counseling in a form other than oral counseling is provided pursuant to Board rules.

(b) Counseling on refill prescriptions shall be such counseling as a reasonable and prudent pharmacist would provide and may include:

(A) Monitoring for compliance;

(B) Intended or expected outcomes;

(C) Adverse drug reaction;

(D) Inquiries about over-the-counter medications;

(E) Generic changes; and

(F) The accuracy of the medication.

(c) A pharmacist may provide counseling in a form other than oral counseling when a reasonable and prudent pharmacist would determine in the particular circumstances that a form of counseling other than oral counseling would be more effective.

(d) Patient counseling shall be in person whenever practicable. Whenever the prescription is delivered outside the confines of the retail drug outlet by mail or other third party delivery, counseling shall be in writing and by free access to the pharmacist by phone.

(e) Before providing professional advice to the patient or patient's agent, the pharmacist shall, when applicable:

(A) Assess the patient, including age, sex, height and weight, chronic medical conditions, medication history, allergies, drug reactions and drug idiosyncrasies, other disease states of the patient, and, when the prescription is a refill, whether the drug has been taken according to the prescriber's directions, therapeutic response and adverse events; and

(B) Perform a drug utilization review as defined by Board rule in OAR 855-006-0005.

(f) When providing professional advice during oral counseling, the pharmacist shall provide such information as a reasonable and prudent pharmacist would provide in the circumstances, which may include:

(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 outcomes;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side effects, common severe adverse effects, common severe 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) Any other information a reasonable and prudent pharmacist would provide relevant to the patient's drug therapy, including information specific to the patient or the drug.

(g) Counseling shall be initiated and provided confidentially.

(2) Patient Records:

(a) 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) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(b) In order to enhance prospective drug review, 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, may be collected.

(c) Patient records shall be maintained for a period of not less than three years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.015
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

**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 & ORS 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 Pharmacies

**855-041-0120**
**Absence of Pharmacist**

(1) General. During such times as hospital pharmacy services are not available, arrangements shall be made in advance by the director for provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy under the standing order of the director.

(2) Night Cabinets. If night cabinets are used, the following shall prevail:

(a) In the absence of a registered pharmacist, medication for inpatients shall be obtained from a locked cabinet(s) or other enclosure(s) located outside the pharmacy to which only a licensed nurse may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. One licensed nurse and only one in any given shift may have access to the night cabinet and may remove drugs therefrom. Such nurse shall be designated in writing by the appro-priate committee of the hospital and shall, prior to being permitted to obtain access to the night cabinet, 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 or designees, who shall require, at a minimum, the following records and procedures:

(A) Drugs can only be removed from the night cabinet on a practitioner's written order, or verbal order which has been reduced to writing;

(B) The practitioner's order shall be left in the night cabinet so that it will be found by a pharmacist and verified for accuracy. The order shall be initialed by both the licensed nurse and the certifying pharmacist.

(b) The director shall, in conjunction with the appropriate committee of the hospital facility, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(A) Such drugs are available therein, properly labeled as designated in OAR 855-041-0130(7);

(B) Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(C) Whenever access to such cabinet(s) shall have been gained, written medical staff orders and proofs of use, if applicable, are provided;

(D) All drugs therein are inventoried no less than once per week;

(E) A complete audit of all activity concerning such cabinet(s) is conducted no less than once per month; and

(F) Written policies and procedures are established to implement the requirements of section (2) of this rule.

(3) Access to Pharmacy. Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this section. One registered nurse supervisor and only one in any given shift may have access to the pharmacy and may remove drugs therefrom. Such nurse shall be designated in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the pharmacy, 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 or designees, who shall require, at a minimum, the following records and procedures:

(a) Drugs can only be removed from the pharmacy on a practitioner's written order, or verbal order which has been reduced to writing;

(b) The practitioner's order shall be left with either the container from which the drug was removed or an identical unit dose and both placed conspicuously so that it will be found by a pharmacist and verified for accuracy. The order shall be initialed by both the nurse supervisor and the certifying pharmacist.

(4) Emergency Outpatient Medication. Hospitals which provide for the dispensing of emergency pharmaceuticals to outpatients during hours when normal community or outpatient hospital pharmacy services are not available may:

(a) Allow a designated nurse supervisor on the original written order of a practitioner as provided in ORS 689.605 to dispense medications pursuant to the following requirements which shall be in the form of pharmacist's standing orders:

(A) A written order of a practitioner authorized to prescribe a drug is presented;

(B) The medication is prepackaged by a pharmacist and contains:

(i) Name, address and telephone number of the hospital;

(ii) 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;

(iii) Accessory cautionary information as required for patient safety;

(iv) 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:

(i) Name of patient;

(ii) Directions for use to the patient;

(iii) Date;

(iv) Identifying number;

(v) Name of prescribing practitioner;

(vi) 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:

(i) Name and address of patient;

(ii) Date of issuance;

(iii) Units issued;

(iv) Initials of supervisor issuing medication.

(F) The original written order is verified by the pharmacist, initialed, dated and filed separately for a period of three years for Board inspection.

(b) Allow practitioners, as provided in ORS 689.225, who are members of the hospital's medical staff, to dispense an emergency supply of medications to patients examined by them in the institution pursuant to the following requirements which shall be in the form of pharmacist's standing orders:

(A) A written order of a practitioner authorized to prescribe a drug is documented in the patient's medical record;

(B) The medication is prepackaged by a pharmacist and contains:

(i) Name, address and telephone number of hospital;

(ii) 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;

(iii) Accessory cautionary information as required for patient safety;

(iv) 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 practitioner that normal services will not be available within 24 hours;

(D) The container is labeled by the practitioner before presenting to the patient and bears the following:

(i) Name of patient;

(ii) Directions for use to the patient;

(iii) Date;

(iv) Identifying number;

(v) Name of prescribing practitioner.

(E) A record of the dispensing is completed by the practitioner for verification by the pharmacists, retained for three years for Board inspection, and shall bear:

(i) Name of patient;

(ii) Date of issuance;

(iii) Medication dispensed;

(iv) Units issued;

(v) Name of practitioner.

(c) Allowed controlled substances to be dispensed to outpatients by the examining practitioner only after the patient has been examined by the practitioner and a legitimate medical need for a controlled substance has been determined.

(5) Emergency Kits:

(a) Emergency Kit Drugs Defined. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of inpatients 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) Supply 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, 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 unmistakably indicate that it 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 supply pharmacist;

(i) Notifications. Whenever an emergency kit is opened or has expired, the supply 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 2-1980, f. & ef. 4-3-80; PB 12-1989, f. & cert. ef. 8-11-89; PB 4-1991, f. & cert. ef. 9-19-91

**855-041-0125**
**Physical Requirements**

(1) Area. The hospital pharmacy shall have floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and meet the other requirements of this section. Floor space shall be allotted to conduct the activities involved with the scope of pharmaceutical services provided.

(2) Equipment and Materials. The hospital pharmacy shall have equipment and physical facilities for proper compounding, dispensing and storage for drugs, including parenteral preparations. As a minimum, the pharmacy shall have the following:

(a) Minimum equipment listed in OAR 855-041-0040, except for the **Official Poison and Exempt Narcotic Register**, provided that if the pharmacy is registered as both an institutional drug outlet and a retail drug outlet, this exception does not apply;

(b) Drugs to meet the needs of the patients of the hospital;

(c) A pharmacy policy and procedures manual.

(3) Storage:

(a) All drugs shall be stored in designated areas within the hospital to insure proper sanitation, temperature, light, ventilation, moisture control, and security;

(b) When drugs are stored on nursing service units, space shall be available at each unit for the storage, safeguarding and preparation of medication doses, and shall include provision of at least the following:

(A) A locked drug cabinet or room shall be equipped to insure physical separation of individual patient prescribed medications. Medications may be stored in secured individual patient storage areas or secured portable storage carts providing separate compartments for individual patients;

(B) A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms;

(C) Alcohol and Flammables. Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.

(4) Unattended Areas. In the absence of a pharmacist, and whenever any area of a hospital pharmacy is not under the personal and direct supervision of a pharmacist, such area shall be locked. All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel. The director shall designate in writing, by title and specific area, those persons who shall have access to particular areas within the pharmacy. 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. Any deviation from the requirements of this section must be approved in writing by the Board.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 475 & ORS 689

Stats. Implemented:

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 12-1989, f. & cert. ef. 8-11-89

**855-041-0130**
**Drug Distribution and Control**

(1) General. The director of pharmacy shall establish 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) Pharmacy Operation and Supervision. A hospital pharmacy shall only be operated under the direct supervision of at least one licensed pharmacist. The pharmacy shall be operated at least part time, five days a week.

(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 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) Preparation and sterilization of parenteral medications manufactured within the hospital;

(b) 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) Establishment of specifications for procurement of all pharmaceutical materials, including drugs, chemicals and biologi-

cals, subject to approval of the appropriate committee of the hospital;

(e) Participation in the development and revisions of a hospital formulary system;

(f) Filling and labeling all containers from which drugs are to be administered;

(g) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient care areas, 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 pharmacy as may be required by state or federal law, and maintenance of accurate control over and accountability for all pharmaceutical materials;

(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.

(6) Practitioner's Orders. All orders for drugs shall be transmitted to the pharmacy by the prescriber or by means of an order format which produces a direct copy or an electronically reproduced facsimile. A pharmacist shall review the practitioner's order before the initial dose of medication is dispensed, provided that in emergencies or when pharmacy services are not available as otherwise contemplated in this division, the medication order shall be reviewed by the pharmacist as soon thereafter as possible. Verification of the accuracy of the medication dispensed and of any transcriptions made of that order shall be documented by the initials of the pharmacist so certifying:

(a) Drug orders for use by inpatients. Orders for drugs for use by inpatients shall, at a minimum, contain: Patient name and location, drug name, strength, directions for use, date and practitioner's signature or signature of practitioner's agent;

(b) Drug orders for use by outpatients. Orders for use by outpatients shall meet the requirements of OAR 855-041-0065.

(7) Labeling:

(a) All drugs intended for use within the facility shall be in appropriate containers and adequately labeled as to identify at a minimum: Brand name or generic name and manufacturer, strength, lot number, and expiration date. An internal code which centrally references manufacturer and lot number can be utilized;

(b) Exemption. As provided in ORS 689.505(1)(b), drugs dispensed by a hospital pharmacy for inpatient use shall be exempt from the labeling requirements of ORS 689.505(5) and OAR 855-041-0065(7) provided that the drugs are to be administered by a health care professional;

(c) Inpatient: All drugs dispensed to individual inpatients other than those dispensed pursuant to section (8) of this rule shall be labeled with the following information:

(A) Identification of pharmacy;

(B) Name and location of patient;

(C) Name of drug;

(D) Route of administration of drug, when necessary for clarification;

(E) Strength of drug;

(F) Auxiliary labels as needed;

(G) Expiration date, if applicable;

(H) Date dispensed.

(d) Outpatient. Labels for outpatient prescriptions shall comply with ORS 689.505(5) and OAR 855-041-0065(7). Drugs originally dispensed to an inpatient shall be returned to the pharmacy for proper labeling before leaving the hospital premises;

(e) Drugs added to parenteral solutions. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and 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, if applicable, administration time and infusion rate when applicable, and name or initials of person so adding.

(8) 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 bed number;

(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;

(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.

(b) Each hospital pharmacy 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 inasfar 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 subsection (7)(c) of this rule.

(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.

(9) Floor Stock/STAT Medication Supplies:

(a) Floor Stock/STAT medication supplies defined. A minimal quantity of medications may be stocked in patient care areas to meet immediate therapeutic patient needs where delay would interrupt the continuity of care;

(b) Limitations. No hospital pharmacy shall utilize a floor stock drug distribution system as its primary system of drug distribution. Such a system, if used, must simply augment the unit-dose drug distribution system in such cases where the quality of patient care is improved or there is an enhancement to drug security and accountability;

(c) Drugs Included. The director of pharmacy and/or pharmacist designee, shall, with input from nursing jointly determine and prepare a written list of drugs by identity and quantity for each area where such supplies are stocked;

(d) Storage. Floor stock/STAT medication supplies shall be stored in a secure area accessible to authorized licensed personnel only;

(e) Labeling. All drugs contained in Floor Stock/STAT medication inventory shall be labeled in accordance with subsection (7)(a) of these rules and regulations;

(f) Removal of Drugs. Drugs shall be removed from Floor Stock/STAT supplies by authorized licensed personnel pursuant to a valid physician's order. Documentation of the removal from stock shall be referenced as directed by policy as well as in the patient's medical record.

(10) Discontinued Drugs. The director shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition, or that the director or his or her designee make proper disposition or dispose of such drugs at the storage site.

(11) Controlled Drug Accountability. The hospital shall establish and implement effective procedures and maintain adequate records regarding use and accountability of controlled substances and such other drugs as the appropriate hospital committee may designate which shall specify at least the following:

(a) Name of drug;

(b) Dose;

(c) Prescriber;

(d) Patient;

(e) Date and time of administration;

(f) Person administering the drug.

(12) Schedule II — Drug Recordkeeping:

(a) Records shall be kept in a readily retrievable form documenting receipt and distribution of all Schedule II drugs by the institutional pharmacy;

(b) These documents shall be made available for Board inspection for the purpose of quantifying any shortages or excesses in Schedule II drugs in the institutional pharmacy;

(c) Schedule II drugs stored as floor stock in patient care areas shall be controlled by a perpetual inventory system which includes an actual inventory count and reconciliation at least once every 24 hours when the department or nursing unit is open;

(d) A random sample of proof of use sheets (sign-out sheets or other dose by dose documentation) shall be performed at least quarterly and used to determine the accuracy and effectiveness of Schedule II floor stock drug control after these drugs leave the physical control of the pharmacy;

(e) All Schedule II drugs stored in the pharmacy shall be kept in a locked storage area whenever a pharmacist is not physically present in the department. Filled prescriptions waiting to be picked up by outpatients are exempt from this requirement;

(f) A perpetual inventory system is required for all Schedule II drugs received, stored and distributed by the institutional pharmacy. The perpetual inventory shall be reconciled with an actual inventory at least monthly with the results and any discrepancies noted on the perpetual inventory.

(13) Recall. The director shall develop and implement a recall procedure that can be readily activated to assure the medical staff of the hospital, the pharmacy staff and the director that all drugs included on the recall, within the hospital, are returned to the pharmacy for proper disposition.

(14) Records and Reports. The recordkeeping requirements of OAR 855-041-0060 and 855-041-0065 shall not apply to hospital inpatient drug orders (as defined in ORS 689.005(12)) except as provided in section (6), subsection (8)(b), and section (14) of this rule and OAR 855-041-0132. The director shall maintain for three years such records and reports as are required to insure patient health, safety and welfare and, at a minimum, the following:

(a) Pharmacy patient profiles and/or medication administration records;

(b) Reports of suspected adverse drug reactions;

(c) Inspections of drug storage areas;

(d) Biennial controlled substances inventories;

(e) Alcohol and flammables reports;

(f) Such other and further records and reports as may be required by law and these rules; and

(g) Controlled drug accountability report.

(15) Drugs from Outside Sources. Whenever patients bring drugs into a hospital, such drugs shall not be administered unless they have been precisely identified by the practitioner or pharmacist; administration shall be pursuant to a practitioner's order specifically by name of drug, strength, and directions for use only. Under no circumstances shall unlabeled, mislabeled, mixed or adulterated drugs be allowed to be used.

(16) Investigational Drugs. All investigational drugs shall be stored in the pharmacy and distributed only from the pharmacy. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs shall be available in the pharmacy. Investigational drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal physician-investigator or his or her authorized clinician(s) with prior approval of the appropriate committee(s) of the hospital and with verifications that the patient (or his legal designee) has signed the informed consent form.

(17) Administration of Drugs:

(a) General. Drugs shall be administered in a hospital only upon the orders of those members of the medical staff who have been granted clinical privileges or who are authorized members of the house staff, or by authorized licensed practitioners in accordance with policies and procedures specified by the appropriate committee of the hospital, under applicable law and rules and regulations and by usual and customary standards of good medical practice;

(b) Self-administration. Self-administration of drugs by patients shall be permitted only when specifically authorized by the treating or ordering practitioner, provided, however, the patient has been educated and trained in the proper manner of self-administration.

(18) Extensions of Pharmacy Services Under Registration. A registered pharmacy in a hospital may utilize additional locations within the hospital without the necessity of securing additional registration provided, however, that the pharmacist in charge of any such hospital pharmacy shall designate another licensed pharmacist to assume professional responsibility, in accordance with ORS 689.315(5) for the practice of pharmacy in each such additional location.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 12-1989, f. & cert. ef. 8-11-89; PB 4-1991, f. & cert. ef. 9-19-91

**855-041-0132**
**Quality Assurance**

Quality Assurance:

(1) The pharmacist-in-charge shall establish written procedures 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. Such monitoring and evaluation are accomplished through the routine collection and periodic assessment of the collected information.

(2) The findings from and conclusions of monitoring, evaluation, and problem solving activities are documented and are made available for Board inspection.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 12-1989, f. & cert. ef. 8-11-89

## 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 Facility and Consulting Pharmacists

### 855-041-0145
### Definitions

As used in OAR 855-041-0145 through 855-041-0160:

(1) "Consulting Pharmacist" means a pharmacist who:

(a) Assists facilities in establishing the policies and procedures for the distribution and storage of drugs;

(b) Visits the facility on a regularly scheduled basis;

(c) Supervises the distribution and storage of drugs; and

(d) Perform quality assurance activities as defined in OAR 855-041-0132.

(2) "Provider Pharmacist" means a pharmacist who supplies medication to the long-term care facility for institutionalized patients.

(3) "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.

(4) "Medication Card" means a medication container, labeled as required in OAR 855-041-0160(9)(c), which provides multiple doses of a single medication with each dose contained in a separate, tamper-evident, sealed compartment.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90

### 855-041-0150
### Absence of Pharmacist (Long-Term Care Facilities)

(1) General. During such time as the long-term care facility pharmacy services are not available, arrangements shall be made in advance by the provider pharmacist for provision of drugs to the staff of the institutional facility by use of an emergency drug supply.

(2) Emergency Drugs:

(a) Emergency Drugs Defined. Emergency drugs are those drugs 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;

(b) The emergency drug supply shall be provided by the provider pharmacist;

(c) Drugs Included. The consulting pharmacist and the practitioner(s) representing the facility shall jointly determine and prepare a list of drugs, by generic name, strength, dosage form and quantity, to be included in the emergency supply. The list of drugs shall be reviewed annually by the appropriate committee. Drugs shall only be available therein, in amounts sufficient for immediate therapeutic requirements. In the case of controlled substances, amounts adequate to meet the unscheduled or periodic needs of patients, may be included;

(d) Security. The emergency drugs supply shall be stored in a manner to prevent loss of drugs, but available to authorized personnel. Controlled substances shall be stored in a locked room, cabinet, or cart. The provider pharmacist shall be notified and a record shall be made that indicates the use of an emergency drug;

(e) 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 within them, as required in official compendia;

(f) 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;

(g) Labeling — Interior. All drugs contained in the emergency medication supply shall be labeled in accordance with OAR 855-041-0130(7)(a);

(h) Removal of Drugs. Emergency drugs shall be removed for administration by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions in 21 CFR 1306.11 and 1306.21 when applicable. Medications may also be removed by the provider pharmacist maintaining the contents;

(i) Notifications. Whenever a drug from the emergency drug supply has been used or has expired, the provider pharmacist shall be notified and the pharmacist shall replace the drug within a reasonable time so as to prevent risk of harm to the patients;

(j) Expiration Date. The expiration date of the emergency drug supply shall indicate the month and the year, and shall be the earliest expiration date of any drug in the supply. On or before the occurrence of the expiration date, the provider pharmacist shall examine the supply and replace expired drugs;

(k) Procedures. The consulting pharmacist shall, in consultation with the appropriate committee, develop and implement written policies and procedures to insure compliance with Board rules.

(3)(a) Access to Facility Pharmacy. Whenever a drug is not available from the emergency drug supply, and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this section. One registered nurse supervisor and only one in any given shift may have access to and remove drugs from the pharmacy, and only in amounts sufficient for immediate therapeutic needs;

(b) Such nurse shall be designated in writing by the appropriate committee of the facility and shall, prior to being permitted to obtain access to the pharmacy, 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 provider pharmacist or designee, who shall require at a minimum, the following records and procedures:

(A) Drugs may only be removed from the pharmacy on a practitioner's written order, or verbal order which has been reduced to writing;

(B) The practitioner's order shall be left with either the container from which the drug was removed or an identical unit dose and both placed conspicuously so that it will be found by a pharmacist and verified for accuracy. The order shall be initialed by both the nurse supervisor and the certifying pharmacist.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 689.155 & ORS 689.205
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90; PB 4-1992, f. & cert. ef. 8-25-92

**855-041-0155**
**Physical Requirements**

(1) Area. The pharmacy serving a long-term care facility as an institutional drug outlet shall have floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and meet the other requirements of this section. Floor space shall be allotted to conduct the activities involved with the scope of pharmaceutical services provided.

(2) Equipment and Materials. The pharmacy serving a long-term care facility as an institutional drug outlet shall have equipment and physical facilities for proper compounding, dispensing and storage for drugs, including parenteral preparations. As a minimum, the pharmacy shall have the following:

(a) Minimum equipment listed in OAR 855-041-0040;

(b) Drugs to meet the needs of the patients of the long-term care facility;

(c) A pharmacy policy and procedures manual.

(3) Storage:

(a) All drugs shall be stored in designated areas within the pharmacy to insure proper sanitation, temperature, light, ventilation, moisture control and security;

(b) Unattended areas. In the absence of a pharmacist, and whenever any area of a pharmacy serving a long-term care facility as an institutional drug outlet is not under the personal and direct supervision of a pharmacist, such areas shall be locked. All areas occupied by a pharmacy serving a long-term care facility as an institutional drug outlet shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel;

(c) When drugs are stored on nursing service units, the consulting pharmacist shall verify that space will be available at each unit for the storage, safeguarding and preparation of medication doses, and shall include provision of at least the following:

(A) A locked drug cabinet or room shall be equipped to insure physical separation of individual patient prescribed medications. Medications may be stored in these secured individual patient storage areas, or secured portable storage carts providing separate compartments for individual patients may be used;

(B) A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
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 8-1990, f. & cert. ef. 12-5-90

**855-041-0160**
**Drug Distribution and Control**

(1) General. The consulting pharmacist shall establish written procedures for the safe and efficient distribution of pharmaceutical products. These procedures shall be available for Board inspection.

(2) Responsibility of the Consulting Pharmacist. The consulting pharmacist shall be responsible for the safe and efficient distribution of, control of and accountability of medications including:

(a) Establishment of specifications for the storage, distribution, and procurement of medications and biologicals, subject to approval of the appropriate committee of the long-term care facility;

(b) Participation in those aspects of the long-term care patient care evaluation program which relate to drug use review;

(c) Providing information on a 24-hour basis for assistance in emergency situations;

(d) Storage of medications in a locked area or locked cart.

(3) Responsibility of the Provider Pharmacist. The pharmacy serving the long-term care facility as an institutional drug outlet shall be responsible for:

(a) The emergency medication supply;

(b) Medications for the long-term care patient, dispensed in a form consistent with the drug distribution system described in the facility's policies and procedures;

(c) Records of all transactions of the provider pharmacy as may be required by law and maintaining accurate control over and accountability for all pharmaceutical materials.

(4) Discontinued Drugs. The consulting pharmacist shall develop and implement policies and procedures to insure that all outdated or improperly labeled drugs or containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Expired, deteriorated or unwanted controlled substances shall be destroyed by introduction to the sewer system, incineration, or other means that will assure protection against unauthorized possession or use. The destruction shall be jointly witnessed on the premises and documented as required in OAR 855-080-0105.

(5) Practitioner's Orders. A pharmacist shall review a medication order, or a copy thereof:

(a) Authorization. Any licensed practitioner authorized by law to prescribe drugs within the scope of his or her license may prescribe for his or her patient in a licensed facility;

(b) Abbreviations. Orders employing abbreviations or chemical symbols shall be only those which are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the appropriate committee of the facility;

(c) Requirements. Orders for drugs for use by patients of the facility shall, at a minimum, contain patient name, drug name and strength, directions for use, and date of order, and name of prescriber. Reorders, shall include all of the above except directions;

(d) Emergency Medication Order. When an emergency medication is ordered when pharmacy services are unavailable, as provided in OAR 855-041-0150(2)(a), the medication order shall be reviewed by the pharmacist as soon as possible;

(e) Verification of the accuracy of any medication dispensed and of any transcriptions made of that order shall be done by handwritten initials of the pharmacist so certifying.

(6) Controlled Drug Accountability. The consulting pharmacist shall establish and implement effective procedures and assure that adequate records are maintained regarding use and accountability of controlled substances which comply with federal and state laws, and specify the following:

(a) Name of drug;

(b) Dose;

(c) Prescriber;

(d) Patient;

(e) Date and time of administration;

(f) Person administering the drug.

(7) Recall. The consulting pharmacist shall develop a recall procedure that can readily be implemented to assure the medical staff of the facility, the pharmacy staff and the consulting pharmacist that all drugs included in the recall, within the facility, are returned to the provider pharmacies for proper disposition. The provider pharmacist shall be responsible for implementing recall procedures when needed.

(8) Records and Reports. The consulting pharmacist shall supervise the maintenance of such records and reports as are required to insure patient health, safety and welfare and, at a minimum, the following:

(a) Pharmacy patient profiles and/or medication administration records;

(b) Written procedures for the distribution of pharmaceuticals in the facility;

(c) Reports of suspected adverse drug reactions;

(d) Inspections of drug storage areas;

(e) Such other and further records and reports as may be required by law;

(f) Controlled drug and accountability reports. These reports must be maintained at the facility for a period of at least three years.

(9) Labeling:

(a) All drugs intended for use within the facility shall be in appropriate containers and adequately labeled as to identify at a minimum: Brand name or generic name and manufacturer, strength, lot number, and expiration date. An internal code which centrally references manufacturer and lot number may be utilized;

(b) Exemption. As provided in ORS 689.505(1)(b), drugs dispensed by an institutional drug outlet to a long-term care facility for inpatient use shall be exempt from the labeling requirements of ORS 689.505 and OAR 855-041-0065(7), provided that the drugs are to be administered by a health care professional;

(c) Inpatient: All drugs dispensed to individual inpatients other than those dispensed pursuant to section (10) of this rule shall be labeled with the following information:

(A) Identification of pharmacy;

(B) Name and location of patient;

(C) Name of drug;

(D) Route of administration of drug when necessary for clarification;

(E) Strength of drug;

(F) Auxiliary labels as needed;

(G) Expiration date, if applicable;

(H) Date dispensed.

(d) Labels for outpatient prescriptions shall comply with ORS 689.505(5) and OAR 855-041-0065(7). Drugs originally dispensed to an inpatient shall be returned to the pharmacy for proper labeling to comply with ORS 689.505(5) and OAR 855-041-0065(7) before leaving the long-term care facility premises;

(e) Drugs Added to Parenteral Solutions. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and 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;

(f) Labeling of Biologicals and Other Injectables. Biologicals and other injectables prescribed and dispensed for an individual patient shall meet the labeling requirements of subsection (9)(c) of this rule. Biologicals and other injectables supplied to a facility for a health immunization or screening program, such as influenza vaccine or tuberculin skin test, and intended for use in the facility, shall contain the following information:

(A) Identification of pharmacy;

(B) Name of facility;

(C) Name of biological or drug;

(D) Route of administration when necessary for clarification;

(E) Strength of biological or drug;

(F) Auxiliary labels as needed;

(G) Expiration date;

(H) Date dispensed;

(I) Lot number.

(g) Labeling of Bulk Medication. Legend irrigation solutions may be stored in the locked medication area of a long-term care facility provided that:

(A) The facility uses the solution only within the confines of the facility and under the orders of an authorized prescriber;

(B) Upon use, the container is identified by patient name;

(C) The container is dated and initialed upon opening;

(D) The solution is stored appropriately after opening according to facility policy. In the event a long-term care facility must treat most or all residents with a non-scheduled prescription medication and the pharmacy can supply such medication in a manufacturer's container providing more than one resident a dose, the facility may store such container in a locked drug room provided:

(i) The facility uses the medication only within the confines of the facility and under the orders of an authorized prescriber;

(ii) The facility uses appropriate technique in dosing from the bulk container to insure no contamination of the remaining doses;

(iii) The bulk container is removed from the facility promptly upon completion of use;

(iv) The facility maintains adequate records to account for all doses used.

(10) 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;

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record system:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the provider or consultant pharmacist to verify the prescriber's original order;

(v) Provide a means for the provider pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient;

(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.

(b) The pharmacy providing services to a long-term care facility as an institutional drug outlet which utilizes 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 inasfar 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;

(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with section (9) of this rule.

(c) The provider 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;

(e) No long-term care facility consulting phar-macist or provider pharmacist shall utilize a floor stock distribution system for prescription drugs.

(11) Stop Orders. An automatic stop order policy shall be adopted and enforced to provide a system to notify the responsible practitioner of the impending expiration of a drug order and to provide a limitation on continuance of medications which are not specifically limited as to time or number of doses when ordered, so that the practitioner may determine whether the drug administration is to be continued or altered.

(12) Drug Delivery Systems. A patient in a long-term care facility must have a choice from among prescription drug delivery systems so long as the system selected:

(a) Provides for timely delivery of drugs;

(b) Provides adequate protection to prevent tampering with drugs;

(c) Provides that drugs are delivered in a unit of use compatible with the established system of the facility for dispensing drugs, whether that system is provided by a facility pharmacy or by contract with a pharmacy;

(d) Provides a 24-hour emergency service procedure either directly or by contract with another pharmacy.

Stat. Auth.: ORS 475 & ORS 689

Stats. Implemented:

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

## 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;

(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;

(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 section (4) of this rule.

(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;

(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 855-041-0177.

(7) 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 689.605 & 689.155
Hist. PB 1-1996, f. & cert. ef. 4-5-96; Administrative correction 11-3-99

## Pharmacists Serving Community-Based Care Facilities

### 855-041-0180
### Definitions as Used in OAR 855-041-0180 through OAR 855-041-0190

(1) "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 twenty-four-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), RCF Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice. Long term care nursing facilities are not included for the purpose of this rule.

(2) "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 under-utilization;

(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 689.015
Hist.: BP 2-1998, f. & cert. ef. 3-23-98

**855-041-0181**
**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 689.015
Hist.: BP 2-1998, f. & cert. ef. 3-23-98

**855-041-0183**
**Emergency Drug Supply in Home Health Care Agencies**

(1) 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:
(a) 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;
(b) 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;
(c) 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.
(d) 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;
(e) 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;
(f) 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;
(g) 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;
(h) 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;
(i) 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;
(j) 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 & ORS 689.205
Stats. Implemented: ORS 689.225
Hist. PB 1-1996, f. & cert. ef. 4-5-96

## Technicians

**855-041-0200**
**Definitions Technicians**

(1) "Pharmacy technician" means a person registered by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board. Persons used solely for clerical duties, record keeping, cashiering, bookkeeping and delivery of medications released by the pharmacist are not considered technicians.
(2) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by a pharmacy technician.
(3) "Supervision by a pharmacist" means being stationed within the same work area as the technician being supervised, coupled with the ability to control and be responsible for the technician's action.
(4) "Prescriptions released by the pharmacist" means, those prescriptions released by the pharmacist that do not require further pharmacist intervention such as reconstitution or counseling.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225
Hist.: PB 3-1989, f. & cert. ef. 1-30-89; 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

**855-041-0203**
**Registration of Technicians**

(1) Pharmacy technicians shall register annually with the Board of Pharmacy on a form approved by the Board.
(2) The registration shall expire on September 30 of each year.
(3) The registration fee and delinquent renewal fee shall be as listed in OAR 855-110-0005.
(4) Pharmacy technicians shall notify the Board in writing within 15 days of a change of home address.
(5) Pharmacy technicians shall notify the Board in writing within 15 days of employment, the name and address of the pharmacy by which they are employed.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225

Hist.: PB 2-1997(Temp), f. 10-2-97, cert. ef. 10-4-97; BP 2-1998, f. & cert. ef. 3-23-98

**855-041-0205**
**Use of Technicians**

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

(2) Technicians shall be supervised by a pharmacist.

(3) Pharmacists pharmacist interns and technicians shall be clearly identified as such to the public.

(4) Work performed by technicians assisting the pharmacist to prepare medications must be verified by a pharmacist prior to release for patient use and the verification must be documented. Verification and documentation must be done in a manner approved by the Board.

(5) No more than two technicians may work under the supervision, direction and control of a pharmacist.

(a) If a pharmacy desires more than two technicians to work under the supervision, direction and control of one pharmacist, the pharmacy shall obtain the written prior approval of the Board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the Board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to, the following:

(A) Design and equipment;

(B) Information systems;

(C) Work flow;

(D) Quality assurance procedures.

(b) The Board shall grant approval of a pharmacy service plan when the Board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the proposed increased use of technicians.

(c) No pharmacy shall modify a Board approved pharmacy service plan without the prior written approval of the Board.

(6) In institutional drug outlets, three technicians may work under the supervision of one pharmacist in performance of the following functions:

(a) Intravenous admixture and other sterile product preparation;

(b) Unit dose dispensing;

(c) Prepackaging;

(d) Bulk compounding; and

(e) Medication card preparation.

(7) Written procedures which describe the tasks performed by the technician and the methods of verification and documentation of work performed by technicians in a pharmacy shall be prepared by the pharmacist-in-charge, and shall be kept on file in the pharmacy for inspection. These procedures shall be reviewed annually and documentation of that review shall be made to the Board on the annual pharmacist-in-charge inspection sheet.

(8) Training:

(a) Technicians shall complete initial training as outlined by the pharmacist-in-charge which includes on-the-job and related education commensurate with the tasks they are to perform, prior to the regular performance of those tasks.

(b) The pharmacist-in-charge shall assure the continuing competency of technicians through in-service education and training to supplement initial training.

(c) A written record of initial and in-service training of technicians shall be maintained and contain the following information:

(A) Name of the person receiving the training;

(B) Date(s) of the training;

(C) General description of the topics covered;

(D) Name of the person supervising the training; and

(E) Signature of the technician and the pharmacist-in-charge.

(9) A pharmacy technician shall keep all patient information confidential, as required in 855-041-0103.

(10) The supervising pharmacist and the pharmacist-in-charge are responsible for the actions of technicians. The use of technicians in the performance of tasks not included in approved written procedures may be considered to be unprofessional conduct on the part of the pharmacist supervising the technician and the pharmacist-in-charge.

(11) Any pharmacy requiring or allowing pharmacists to use technicians in violation of the Oregon pharmacy act or Board rules is subject to revocation, suspension, or restriction of the drug outlet registration as well as a fine of $1,000 for each offense.

(12) The pharmacy shall maintain on file the current certificate of registration of each pharmacy technician.

(13) Prior to utilizing any person as a technician, the pharmacy shall obtain verification that the person is currently registered as a pharmacy technician.

(14) No pharmacy shall knowingly utilize, without written Board approval, any person as a pharmacy technician who has been:

(a) Convicted of any crime or offense involving dishonesty or involving drugs;

(b) Disciplined by a Board of Pharmacy in any other state; or

(c) Licensed as a pharmacist or pharmacist intern in this or any other state and has been disciplined or has surrendered his/her license.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225
Hist.: PB 3-1989, f. & cert. ef. 1-30-89; PB 15-1989, f. & cert. ef. 12-26-89; PB 5-1990, f. & cert. ef. 4-12-90; PB 4-1991, f. & cert. ef. 9-19-91; PB 2-1997(Temp), f. 10-2-97, cert. ef. 10-4-97; BP 2-1998, f. & cert. ef. 3-23-98

**855-041-0210**
**Duties of Pharmacist**

(1) Only a registered pharmacist or pharmacist-intern may perform the following:

(a) Receive a new prescription order verbally from a prescriber or other person authorized by law;

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system;

(c) Perform identification, evaluation, interpretation and any needed clarification of a prescription.

(d) Consult with the prescriber or the prescriber's agent regarding a patient and any medical information pertaining to his or her prescription;

(e) Interpret the clinical data in a patient medication record system; and

(f) Perform professional consultation with any prescriber, nurse or other health care professional or authorized agent.

(g) Counsel the patient or the patient's agent on a prescription or a nonprescription drug.

(2) Only a registered pharmacist may perform the following:

(a) Verify the prescription prior to release for patient use;

(b) Select for purchase a drug product for dispensing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225
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

**855-041-0300**
**Out-of State Pharmacies**

(1) Every out-of-state pharmacy that delivers prescription drugs and/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 licensed/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, who shall be responsible for all prescription drugs and/or or 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 be in good standing with that licensing board.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented:
Hist.: PB 1-1994, f. & cert. ef. 2-2-94

**855-041-0400**
**Collaborative Drug Therapy Management Arrangement**

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

(a) The identification, either by name or by description, of the participating pharmacist(s);

(b) The identification, by name of the participating practitioner(s);

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

(d) A detailed description of the collaborative role the pharmacist(s) shall play, including but not limited to:

(A) Whether the pharmacist will be initiating, modifying, or continuing drug therapy;

(B) Guidelines upon which pharmacist decisions to initiate, modify, or continue drug therapy are based;

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

(D) Quality assurance and periodic review by a panel of the participating pharmacist(s) and practitioner(s).

(e) Authorization by the practitioner(s) for the pharmacist(s) to participate in the collaborative drug therapy arrangement;

(f) A provision for the practitioner to prohibit implementation of the arrangement for an identified individual patient;

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

(h) A description of the mechanism for the pharmacist(s) to communicate to the practitioner(s) and for documentation of the implementation of the collaborative drug therapy arrangement.

(2) A collaborative drug therapy management arrangement is valid only when:

(a) Entered into between one pharmacist and one practitioner; or

(b) Entered into by one or more pharmacists at a single pharmacy registered by the board and two or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice.

(3) The collaborative drug therapy management arrangement must be kept on file in the pharmacy for inspection by the Board of Pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(30)
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

## 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 radiopharma-ceutical.

(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 radio-pharmaceuticals 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 non-radio-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 nonradiopharma-ceuticals 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.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 475.035 & ORS 689.205

Stats. Implemented:

Hist.: PB 7-1987, f. & ef. 7-8-87; PB 1-1994, f. & cert. ef. 2-2-94

**855-042-0020**

**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 State Radiation Control Agency; and

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

(3) Submit to the Board of Pharmacy either:

(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; or

(b) Certification of completion of a nuclear pharmacy training program in an accredited college of pharmacy; or

(c) That upon application to the board in affidavit form, and upon the furnishing of such other information as the Board may require, the Board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy, if, in the opinion of the Board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited college of pharmacy; and

(d) Evidence of current certification in nuclear pharmacy by the Board of Pharmaceutical Specialties.

(4) Receive a letter of notification from the Board of Pharmacy that the evidence submitted that the pharmacists meets the requirements of sections (1), (2), and (3) of this rule has been accepted by the Board and that, based thereon, the pharmacist is recognized by the Board as a nuclear pharmacist.

Stat. Auth.: ORS 475.035 & ORS 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**

**Practitioner Labeling**

All drugs dispensed by a practitioner shall 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 shall also contain the name of the manufacturer or distributor;

(5) Direction for use;

(6) Required precautionary information regarding controlled substances;

(7) Such other and further accessory cautionary information as required for patient safety; and

(8) An expiration date after which the patient should not use the drug or medicine. Expiration dates on drugs dispensed must be the same as that on the original container unless, in the practitioners 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.

Stat. Auth.: ORS 689.155 & ORS 689.205
Stats. Implemented:
Hist.: PB 4-1992, f. & cert. ef. 8-25-92

## Non-Pharmacy Dispensing Drug Outlets

## County Health Clinics

**855-043-0110**
**Purpose and Scope**

(1) A registered nurse who is an employee of a local health department established under the authority of a county or district board of health and registered by the board under ORS 689.305 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 the Health Division.

Stat. Auth.: ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315
Stats. Implemented:
Hist.: PB 2-1992, f. & cert. ef. 3-26-92

**855-043-0120**
**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 by:

(a) A practitioner of the authorized agent thereof;

(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 approved by the Board and the Health Division for dispensing by registered nurse employees of county health clinics. The formulary shall not include controlled substances.

(4) "Health Officer" means a physician licensed by the Board of Medical Examiners for the State of Oregon and employed by or under contract with a county or district health department or the State Health Division.

Stat. Auth.: ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315
Stats. Implemented:
Hist.: PB 2-1992, f. & cert. ef. 3-26-92; PB 4-1992, f. & cert. ef. 8-25-92

**855-043-0130**
**Drug Delivery and Control**

(1) Policies and Procedures. The health officer shall be held responsible for the following:

(a) Written policies and 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) Drugs shall be personally dispensed either by the health officer or by a registered nurse;

(b) Drugs shall be dispensed in containers complying with the federal Poison Prevention Packaging Act unless the patient requests a non-complying container;

(c) Registered nurses shall only dispense drugs listed in the formulary;

(d) The health officer or a registered nurse shall label prescription drugs 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, as approved by the Board, shall accompany all drugs dispensed from a county health clinic.

(3) Repackaged Drugs. Drugs repackaged for dispensing 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 a 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 the health officer or of a registered nurse, drugs shall be kept in a locked drug cabinet or drug room which is sufficiently secure to deny access to unauthorized persons. Only the health officer and registered nurses shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room shall remain locked;

(b) All drugs shall be stored in areas which will assure proper sanitation, temperature, light, ventilation and moisture control as required in official compendium (such as the **United States Pharmacopeia** and **National Formulary**);

(c) Drugs which 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.

(5) Drug Records;

(a) A dispensing records shall be maintained separately from the patient chart and kept for a minimum of three years. The record shall 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 dispersal of drugs shall be kept for a minimum of three years;

(c) All records required by these rules or by federal and state law shall be readily retrievable and available for inspection by the Board.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented:
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

## Student Health Centers

**855-043-0200**
**Purpose and Scope**

(1) A nurse practitioner authorized to write prescriptions under ORS 678.390 and employed by a college or university student health center registered by the Board under ORS 689.305 shall be authorized to dispense drugs to the practitioner's patients, if the patients are students of the college or university.

(2) Students shall be given the choice of taking their prescription to a community pharmacy located off campus.

(3) Drugs dispensed shall be prepackaged by a pharmacy registered by the Board or repackaged by a manufacturer registered by the Board.

(4) Such dispensing shall be limited to those agents in the following therapeutic classes for which the nurse practitioner is authorized to write prescriptions under ORS 678.390. Dispensing from asterisked therapeutic classes shall be limited to a seven day supply.

(a) Oral Contraceptives;
(b) Contraceptive Devices;
(c) Anti-infectives;
(d) Anti-inflammatories;
(e) Decongestants;
(f) Antihistamines*;
(g) Analgesics;
(h) Antidepressants*;
(i) Antitussives/Expectorants;
(j) Gastrointestinals*;
(k) Inhaled metered dose bronchodilators and anti-inflammatories;
(l) Prenatal Vitamins.

(5) The nurse practitioner and the consultant pharmacist shall together decide which individual drugs to stock from the listed therapeutic classes.

(6) The consultant pharmacist shall conduct, on an inspection form provided by the Board, an annual inspection of the student health center by February 1. The completed report form shall be filed in the student health center, be available to the Board for inspection, and be kept on file for three years.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented: ORS 689.155 & ORS 689.605
Hist.: PB 2-1994, f. & cert. ef. 6-1-94; PB 1-1996, f. & cert. ef. 4-5-96

**855-043-0205**
**Drug Delivery and Control**

(1) Policies and Procedures. A pharmacist licensed by the board shall establish procedures for the following:

(a) 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) Drugs shall be dispensed to the student by the nurse practitioner only when the student health center pharmacy is closed or does not exist;

(b) Drugs shall be prepackaged by a pharmacy or manufacturer and provide on the label:

(A) The 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 on the label;
(B) The quantity of the drug;
(C) Cautionary statements, if any, required by law;
(D) The name, address, and phone number of the student health center; and
(E) The manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(c) The nurse practitioner shall label prescription drugs with the following information:

(A) Name of the patient;
(B) Name of the prescriber;
(C) Date of dispensing; and
(D) Directions for use.

(d) The nurse practitioner shall personally dispense drugs to the patient;

(e) Drugs shall be dispensed in containers complying with the federal Poison Prevention Packaging Act, unless the patient requests a non-complying container;

(f) The pharmacist and the nurse practitioner shall provide a means for patients to receive verbal and written information on drugs dispensed to the patient. The written drug information shall include:

(A) Drug name and class;
(B) Proper use and storage;
(C) Common side effects;
(D) Precautions and contraindications; and
(E) Significant drug interactions.

(3) Drug Utilization Review:

(A) "Drug utilization review" means the collaborative review by the nurse practitioner and the pharmacist of the patient records, including but not limited to drugs prescribed and dispensed, dosage, duration of therapy, allergies, interactions, and compliance;

(b) The nurse practitioner and the pharmacist shall perform regular drug utilization reviews at least quarterly, sign health center for a minimum of three years;

(c) All records and information that are the subject of a drug utilization review are confidential and shall not be disclosed, except as specifically authorized or required by law.

(4) Drug security, storage and disposal:

(a) In the absence of the nurse practitioner or the pharmacist, drugs shall be kept in a locked cabinet or drug room which is sufficiently secure to deny access to unauthorized persons. Only the nurse practitioner and the pharmacist shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room shall be kept locked;

(b) All drugs shall be stored in areas which will assure proper sanitation, temperature, light, ventilation, and moisture control as required in official compendium, such as the **United States Pharmacopeia** or **National Formulary**;

(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated shall be physically separated from other drugs until they are destroyed or returned to their supplier;

(d) Controlled substances which are expired, deteriorated, or unwanted shall be disposed of in conformance with **21 CFR 1307.21**.

(5) Drug records:

(a) A drug dispensing record shall be maintained separately from the patient record and kept for a minimum of three years. The dispensing record shall show, at a minimum, the following:

(A) Name of patient;
(B) Brand name of drug, or generic name and manufacturer or distributor;
(C) Date of dispensing; and
(D) Initials of nurse practitioner.

(b) All records of receipt and dispersal of drugs shall be kept for a minimum of three years;

(c) All records required by these rules or by federal or state law shall be readily retrievable and available for inspection by the board.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 689.155 & ORS 689.205
Stats. Implemented:
Hist.: PB 2-1994, f. & cert. ef. 6-1-94

## DIVISION 46

## OPERATION OF VETERINARY DRUG OUTLETS

**855-046-0001**
**Definitions**

(1) "Veterinary Drug Outlet" means a drug outlet that distributes drugs for use in animals but does not include a veterinary medical facility as defined in OAR 875-015-0000 or a pharmacy as defined in ORS 689.005

(2) "Prescription Drug" or "legend drug" means a drug which is:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of the following statements:

(A) "Caution: Federal law prohibits dispensing without prescription"; or

(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

(3) "Distribute" means the delivery of a drug other than by administering or dispensing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

**855-046-0005**
**Veterinary Drug Outlet Applications**

(1) All applications for registration of a new or relocated veterinary drug outlet shall be accompanied by the required fees as set forth in 855-110-0007 and 855-110-0010.

(2) Application shall specify the location of the veterinary 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 September 30 of the current year, a delinquent fee as set forth in OAR 855-110-0005 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 veterinary drug 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.

(9) If there is more than one veterinary 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

**855-046-0020**
**Minimum Standards for Veterinary Drug Outlets**

(1) Veterinary drug outlets shall have floor space and shelving to insure that veterinary drugs are stocked and stored in sanitary, well-lighted areas. Where applicable, temperature, ventilation and moisture controls shall be employed.

(2) Expiration dates on veterinary drug outlet drugs shall be the responsibility of each veterinary drug outlet to insure products are in date.

(3) There shall be no advertisements of any kind by a veterinary drug outlet using the following or similar terms: "drug store," "pharmacy," "apothecary."

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

**855-046-0030**
**Change of Business Name, Closure**

(1) Any change of business name of a veterinary 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 veterinary drug outlet shall be reported to the Board within 15 days.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

**855-046-0040**
**Distribution of Veterinary Drugs**

Veterinary drug outlets shall not distribute prescription veterinary drugs. Veterinary drug outlets may distribute nonprescription veterinary drugs in the original and unbroken packages only, properly labeled according to state and federal law, in conformity with rules of the Board. No veterinary drug outlet shall purchase or receive veterinary drugs from a source not registered with the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

**855-046-0050**
**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 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

**855-046-0060**
**Return to Stock**

No veterinary drug product shall be returned to stock once it has been distributed and removed from the drug outlet unless it is a nonperishable product and is in its original unbroken or otherwise unopened container.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005(10), ORS 689.005(12), ORS 689.005(21) & ORS 689.305
Hist.: BP 3-1998, f. & cert. ef. 3-23-98

## 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 (H2S04) 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

**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**"; or
(B) "**Caution: Federal law restricts this drug to be used by or on the order of a licensed veterinarian**."
(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;
(c) Preparations containing ephedrine or salts of ephedrine.
(3) The following brand name products and their generic equivalents are exempt from designation as prescription drugs under section (2) of this rule:
(a) Amesec Capsules;
(b) Bronc Ease Plus;
(c) Bronitin Tablets;
(d) Bronkotabs;
(e) Bronkolixir;
(f) Bronkaid Tablets;
(g) Efedron Nasal Jelly;
(h) Guiaphed Elixir;
(i) Haysma;
(j) Pazo Hemmorrhoid Ointment and Suppositories;
(k) Primatene "M" Formula Tablets;
(l) Primatene "P" Formula Tablets;
(m) Primatene Tablets;
(n) Tedrigen Tablets;
(o) Tedral Tablets, Suspension and Elixir;
(p) T.E.P.;
(q) Vatronol Nose Drops.
(4) No person shall sell, give away, barter, transfer, purchase, receive or possess prescription drugs except upon the prescription of a practitioner.
(5) Manufacturers, wholesalers, institutional and retail drug outlets and practitioners are exempt from the prohibition of section (4) of this rule.
Stat. Auth.: ORS 475 & ORS 68
Stats. Implemented:
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

## DIVISION 55

## DMSO

**855-055-0005**
**Definitions**
As used in OAR 855-055-0010 through 855-055-0020:
(1) "DMSO" means Dimethyl Sulfoxide; and
(2) "Prescription" means the written direction of a licensed physician for the preparation and use of DMSO as a drug.
Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 4-1982, f. & ef. 8-6-82

**855-055-0010**
**Labeling**
All DMSO sold in Oregon, other than by prescription, shall be labeled by the manufacturer or, if not by the manufacturer, the seller, with information as follows affixed to the container:
(1) The percent of DMSO in the solution.
(2) A description of all the contents in the solution.
(3) A statement of the purity of the DMSO, the diluent, and any other content named in the solution.
(4) That the product is not being sold as a medicine or drug.
(5) That no medical or other applications to the human body are advised or promoted for the product, and that such usage may be harmful.
(6) That DMSO is quickly absorbed through the skin and can carry contaminants and impurities with it.
(7) That care should be exercised to avoid skin contact and to wear protective gloves and clothing when using the product.
(8) The manufacturer's name and address; and
(9) If repacked, the repacker shall place his name and address on the label.
Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 4-1982, f. & ef. 8-6-82

**855-055-0015**
**Cautionary Statements**
All cautionary statements shall be in 7 points Helvetica Regular Letters and printed in red to differentiate them from the rest of the label that shall be printed in a color other than red.
Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 4-1982, f. & ef. 8-6-82

**855-055-0020**
**Penalties**
Violations of any requirement of OAR 855-055-0010 or 855-055-0015 is subject to a civil penalty of not less than $100 and not more than $500 for the first violation, and not less than $500 and not more than $1,000 for any subsequent violation.
Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 4-1982, f. & ef. 8-6-82

## 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), 689.005(35), and 689.005(36) shall be conducted or operated until it has been registered by the State Board of Pharmacy. Manufacturing registration expires June 30 annually:

(1) All applications for registration of a new or relocated manufacturer shall be accompanied by the required fees as set forth in OAR 855-110-0005(8).

(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 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) 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 475.035 & ORS 689.205
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94

**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 & ORS 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, ORS 689.155, ORS 689.205, ORS 689.305 & ORS 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 & ORS 689.205
Stats. Implemented:
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94

## DIVISION 65

## WHOLESALE DRUG OUTLETS

**855-065-0001**
**Application**

Every wholesale drug outlet, wherever located, who engages in wholesale distribution into, out of, or within this state must be registered by the Board in accordance with the laws and regulations of this state before engaging in wholesale distribution of drugs:

(1) The Board requires the following from each wholesale drug outlet as part of the initial registration procedure and as part of any renewal of such registration:

(a) The name, full business address, and telephone number of the registrant;

(b) All trade or business names used by the registrant;

(c) Addresses, telephone numbers, and the names of contact persons for the facility used by the registrant for the storage, handling, and distribution of prescription drugs;

(d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(e) The name(s) of the owner and/or operator of the registrant, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(2) Where operations are conducted at more than one location by a single wholesale drug outlet, each such location shall be registered by the Board.

(3) Changes in any information in this section shall be submitted to the Board within 15 days after such change.

(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 fee cannot be prorated.

Stat. Auth.: ORS 475.035 & ORS 689.205
Stats. Implemented:
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

**855-065-0005**
**Definitions**

(1) "Blood" means who blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) "Blood Component" means that part of blood separated by physical or mechanical means.

(3) "Drug Sample" means a unit of a drug that is not intended to be sold and is intended to promote the sale of the drug.

(4) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(5) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(6) "Wholesale Distribution" means distribution of drugs to persons other than a consumer or patient, but does not include:

(a) 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 drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;

(b) The dispensing of a drug pursuant to a prescription;

(c) The lawful distribution of drug samples by manufacturers representatives or distributors' representatives; or

(d) The sale, purchase, or trade of blood and blood components intended for transfusion;

(e) Intracompany sales.

(7) "Wholesale Drug Outlet" means anyone engaged in wholesale distribution of drugs, including but not limited to manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and pharmacies that conduct wholesale distributions and their officers, agents, representatives and employees:

(a) "Class I Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which 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 whole sale distribution center, wholesale business or any other business in which nonprescription drugs are offered for sale at wholesale to a retail store legally authorized to resell.

Stat. Auth.: ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315
Stats. Implemented:
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)

**855-065-0007**
**Minimum Qualifications**

(1) The Board may deny an application for an initial registration or renewal of registration as a wholesale drug outlet on the following grounds:

(a) Being found by the Board or by a court to have violated the pharmacy or drug laws or rules of this state or laws or rules of any state or of the federal government;

(b) Any conviction of the applicant under federal, state, or local laws;

(c) The applicant's history of compliance in the manufacture, distribution, or dispensing of drugs, including controlled substances;

(d) The making of a material misrepresentation the Board in the course of applying for an initial;

(e) Disciplinary action 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;

(f) Has engaged in conduct involving moral turpitude;

(g) The Board determines that granting the registration is not consistent with the public health or safety or is otherwise not in the public interest.

(2) The Board reserves the right to deny a registration to an applicant if it determines that the granting of such a registration would not be in the public interest.

Stat. Auth.: ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315
Stats. Implemented:
Hist.: PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92)

**855-065-0009**
**Personnel**

The wholesale drug outlet shall employ adequate personnel with the education and experience necessary to safety and lawfully engage in the whole sale distribution of drugs.

Stat. Auth.: ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315
Stats. Implemented:
Hist.: PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92)

**855-065-0010**
**Minimum Requirements for the Storage and Handling of Drugs and for the Establishment and Maintenance of Drug Distribution Records**

Wholesale drug outlets are required to store and handle drugs, and establish and maintain records as follows:

(1) Facilities: All facilities at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) Be of suitable size and construction for cleaning, maintenance, and proper operations;

(b) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a area for the storage of quarantined drugs;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds or vermin of any kind.

(2) Security:

(a) All facilities used for wholesale drug distribution shall be secure from unauthorized entry:

(A) Access from outside the premises shall be kept to a minimum and be well-controlled;

(B) The outside perimeter of the premises shall be well-lighted;

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours;

(c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) Storage: All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium:

(a) If no storage requirements are established for a drug, the drug may be held at "controlled" room, temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected;

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs;

(c) The record keeping requirements in section (6) of this rule shall be followed for all drugs.

(4) Examination of Materials:

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(b) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(5) Returned, Damaged, and Outdated Drugs:

(a) 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;

(b) Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier;

(c) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug outlet shall consider among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(6) Record Keeping:

(a) Wholesale drug outlets shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

(A) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(B) The identity and quantity of the drugs received and distributed or disposed of; and

(C) The dates of receipt and distribution or other disposition of the drugs.

(b) Inventories and records shall be made available for inspection and photocopying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, law enforcement agencies, and this Board;

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart, from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request;

(d) Inventories and records required under these rules shall be maintained for a period of three years following disposition of the drugs.

(7) Written Policies and Procedures: Wholesale drug outlets shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug outlets shall include in their written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary an appropriate;

(b) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(A) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement of other government agency, including the Board;

(B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that whole sale drug outlets prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(d) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

(8) Responsible Persons: Wholesale drugs outlets shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(9) Compliance with federal, state, and local law: Wholesale drug outlets shall operate in compliance with applicable federal, state and local laws and regulations:

(a) Wholesale drug outlets shall permit the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in reasonable manner;

(b) Wholesale drug outlets that deal in controlled substances shall register with the Board and with the Drug Enforcement Administration (D.E.A.), and shall comply with all applicable state, local, and D.E.A. regulations.

(10) Salvaging and Reprocessing: Wholesale drug outlets shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to drug product salvaging or reprocessing, including **Chapter 21, Parts 207, 210, 211** of the **Code of Federal Regulations**.

(11) Delivery of Drugs: Wholesale drug outlets may deliver drugs by:

(a) Common carrier;

(b) U.S. Postal Service;

(c) Wholesaler-operated vehicles.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 689.155, ORS 689.205, ORS 689.305 & ORS 689.315

Stats. Implemented:

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)

## DIVISION 70

## PROPHYLACTICS AND CONTRACEPTIVES

[ED. NOTE: The following rules 855-070-0005 through 855-070-0020 were promulgated with the cooperation of the Oregon State Health Division (ORS 435.100).]

### 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 & ORS 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 wholesale that intends to distribute either male or female condoms shall furnish to the Board the names of such products and a sample of each condom, as packaged for distribution.

(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.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 689.155 & ORS 689.205
Stats. Implemented:
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

### 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 & ORS 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 OAR 855-080-0020 and 855-080-0025:

(1) "Act" means the Uniform Controlled Sub-stances Act, ORS Chapter 745, and rules thereunder.

(2) "CFR" means **Code of Federal Regulations**.

(3) "U.S.C." means **United States Code**.

(4) Terms not defined in this rule have the definition set forth in ORS 475.005.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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; PB 5-1991, f. & cert. ef. 9-19-91

### 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 457.035 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.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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; 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

### 855-080-0021
### Schedule I

Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in this rule:

(1) Opiates. 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) Acetyl-Alpha-Methylfentanyl;

(b) Acetyimethadol;

(c) Allylprodine;

(d) Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadylacetate, or LAAM);

(e) lphameprodine;

(f) Alphamethadol;

(g) Alpha-methylfentanyl;

(h) Alpha-methylthiofentanyl;

(i) Benzethidine;

(j) Benzlfentanyl;
(k) Betacetylmethadol;
(l) Beta-hydroxyfentanyl;
(m) Beta-hydroxy-3-methylfentanyl;
(n) Betameprodine;
(o) Betamethadol;
(p) Betaprodine;
(q) Clonitazene;
(r) Dextromoramide;
(s) Diampromide;
(t) Diethylthiambutene;
(u) Difenoxin;
(v) Dimenoxadol;
(w) Dimepheptanol;
(x) Dimethylthiambutene;
(y) Dioxaphetyl butyrate;
(z) Dipipanone;
(aa) Ethylmethylthiambutene;
(bb) Etonitazene;
(cc) Etoxeridine;
(dd) Furethidine;
(ee) Hydoxypethidine;
(ff) Ketobemidone;
(gg) Levomoramide;
(hh) Levophenacylmorphan;
(ii) 3-methylfentanyl;
(jj) 3-methylthiofentanyl;
(kk) Morpheridine;
(ll) MPPP (1-methyl-4 phenyl-4 propionoxipiperidine);
(mm) Noracymethadol;
(nn) Norlevorphanol;
(oo) Normethadone;
(pp) Norpipanone;
(qq) Para-fluorofentanyl;
(rr) PEPAP (1-(2 phenethyl)-4-phenyl-4-acetoxypiperidine);
(ss) Phenadoxone;
(tt) Phenampromide;
(uu) Phenomorphan;
(vv) Phenoperidine;
(ww) Piritramide;
(xx) Proheptazine;
(yy) Properidine;
(zz) Propiram;
(aaa) Racemoramide;
(bbb) Thenylfentanyl;
(ccc) Thofentanyl;
(ddd) Tilidine;
(eee) Trimeperidine.

(2) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any quantity of the following of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(a) Acetorphine;
(b) Acetyldihydrocodeine;
(c) Benzylmorphine;
(d) Codeine methylbromide;
(e) Codeine-N-Oxide;
(f) Cyprenorphine;
(g) Desomorphine;
(h) Dihydromorphine;
(i) Drotebanol;
(j) Etorphine (except hydrochloride salt);
(k) Heroin;
(l) Hydromorphinol;
(m) Methyldesorphine;
(n) Methyldihydromorphine;
(o) Morphine methylbromide;
(p) Morphine methylsulfonate;
(q) Morphine-N-Oxide;
(r) Myrophine;
(s) Nicocodeine;
(t) Nicomorphine;
(u) Normorphine;
(v) Pholcodine;
(w) Thebacon.

(3) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this section only, the term "isomer" includes the optical position and geometric isomers):
(a) Alpha-ethyltryptamine;
(b) 4 Bromo-2,5-dimethoxy-amphetamine;
(c) 4-bromo-2,5-dimethoxyphenethylamine;
(d) 2,5 dimethoxyamphetamine;
(e) 2,5 dimethoxy-4-ethylamphetamine;
(f) 4-methoxyamphetamine;
(g) 5-methoxy-3,4-methylenedioxy-amphetamine;
(h) 4-methyl-2,5-dimethoxy-amphetamine;
(i) 3,4-methylendioxy amphetamine;
(j) 3,4-methylendioxy methamphetamine (MDMA);
(k) 3,4-methylenedioxy-N-ethylamphetamine (MDA, MDE, MDED);
(l) N-hydroxy- 3,4-methylenedioxyamphetamine (N-hydroxy MDA);
(m) 3,4,5-trimethoxy amphetamine;
(n) Bufotenine;
(o) Diethyltryptamine;
(p) Dimethyltryptamine;
(q) Ibogaine;
(r) Lysergic acid diethylamide;
(s) Marihuana;
(t) Mescaline;
(u) Parahexyl;
(v) Peyote — Meaning all parts of the plant presently classified botanically as *lophophora williamsii* Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds and extracts;
(w) N-ethyl-3-piperidyl benzilate;
(x) N-methyl-3-piperidyl benzilate;
(y) Psilocybin;
(z) Psilocyn;
(aa) Tetrahydrocannabinols;
(bb) Ethylamine analog of phencyclidine;
(cc) Pyrrolidine analog of phencyclidine;
(dd) Thiophene analog of phencyclidine;
(ee) 1-[1-(2-thienyl) cyclohexyl] pyrrolidine.

(4) Depressants. Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(a) Mecloqualone;
(b) Methaqualone.

(5) Stimulants. Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including its salts, isomers, and salts of isomers:
(a) Aminorex;
(b) Cathinone;
(c) Fenethylline;
(d) Methcathinone;
(e) (+) cis-4-methylaminorex;
(f) N-ethylamphetamine;
(g) N-N Dimethylamphetamine.

Stat. Auth.: ORS 475.035
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 1-1994, f. & cert. ef. 2-2-94; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1997, f. & cert. ef. 9-22-97

**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 this rule:

(1) **Substances, vegetable origin or chemical synthesis**. Unless specifically excepted or unless listed in another schedule, any quantity of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, dextrophan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

(A) Raw opium;
(B) Opium extracts;
(C) Opium fluid;
(D) Powdered opium;
(E) Granulated opium;
(F) Tincture of opium;
(G) Codeine;
(H) Ethylmorphine;
(I) Etorphine hydrochloride;
(J) Hydrocodone;
(K) Hydromorphone;
(L) Metopon;
(M) 6-monoacetyl morphine;
(N) Morphine;
(O) Oxycodone;
(P) Oxymorphone;
(Q) Thebaine.

(b) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subsection (a) of this section except that these substances shall not include the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Cocaine, including its salts, isomers (whether optical or geometric) and salts of such isomers; coca leaves, and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecognine.

(e) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy).

(2) **Opiates**. Unless specifically excepted or unless listed in another schedule any quantity of the following substances, including its 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, dextrorphan and levopropoxyphene excepted:

(a) Alfentanil;
(b) Alphaprodine;
(c) Anileridine;
(d) Bezitramide;
(e) Bulk Dextropropoxyphene (non-dosage forms);
(f) Carfentanil;
(g) Dihydrocodeine;
(h) Diphenoxylate;
(i) Fentanyl;
(j) Isomethadone;
(k) Levo-alphacetylmethadol (levo-alphaacetylmethadol, levomethadyl acetate, LAAM);
(l) Levomethorphan;
(m) Levorphanol;
(n) Metazocine;
(o) Methadone;
(p) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
(q) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
(r) Pethidine (meperidine);
(s) Pethidine-Intermediate-A, 4-cyano-1-methyl-4, phenylpiperidine;
(t) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
(u) Pethidine-Intermediate-C, 1 methyl-4-phenylpiperidine-4-carboxylic acid;
(v) Phenazocine;
(w) Piminodine;
(x) Racemethorphan;
(y) Racemorphan;
(z) Sufentanil.

(3) **Stimulants**. Unless specifically excepted or listed in another schedule, any quantity of the following substances:

(a) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(b) Methamphetamine, its salts, isomers, and salts of its isomers.

(c) Phenmetrazine and its salts.

(d) Methylphenidate.

(4) **Depressants**. Unless specifically excepted or listed in another schedule, any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Amobarbital;
(b) Glutethimide;
(c) Pentobarbital;
(d) Phencyclidine;
(e) Secobarbital.

(5) **Hallucinogenic Substances**: Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation: Nabilone.

(6) **Immediate precursors**. Unless specifically excepted or listed in another schedule, any quantity of the following substances:

(a) Immediate precursor to amphetamine and methamphetamine: Phenylacetone.

(b) Immediate precursors to phencyclidine:
(A) 1-phenylcyclohexylamine;
(B) 1-piperidinocyclohexanecarbonitrile (PCC).

(7) **Other Substances**. Unless specifically excepted or listed in another schedule, any quantity of the following substances or their salts or stereoisomers:

(a) Anthranilic acid;
(b) Ephedrine;
(c) Hydriodic acid;
(d) Methylamine;
(e) Methylformamide;
(f) Lead Acetate;
(g) Phenylacetic acid;
(h) Pseudoephedrine.

(8) A substance containing ephedrine, or any of its salts or stereoisomers, or pseudoephedrine, or any of its salts or stereoisomers or any cosmetic which is prepared for dispensing or over-the-counter distribution and is in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations is not a controlled substance for the purpose of this section.

Stat. Auth.:ORS 689.205
Stats. Implemented: ORS 475.035
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

**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 this rule:

(1) **Stimulants**. Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Section 1308.32 of **Title 21** of the **Code of Federal Regulations**, and any other drug of the quantitive composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances.

(b) Benzphetamine;

(c) Chlorphentermine;

(d) Clortermine;

(e) Phendimetrazine.

(2) **Depressants**. Unless specifically excepted or listed in another schedule, any quantity of the following substances:

(a) In a compound, mixture or preparation containing:

(A) Amobarbital;

(B) Secobarbital;

(C) Pentobarbital;

(D) A salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

(b) In a suppository dosage form containing:

(A) Amobarbital;

(B) Secobarbital;

(C) Pentobarbital;

(D) Salts of any of these drugs which have been approved by the Food and Drug Administration for marketing as a suppository.

(c) Derivatives of barbituric acid or any salt thereof.

(d) Chlorhexadol.

(e) Ketamine.

(f) Lysergic acid.

(g) Lysergic acid amide.

(h) Methyprylon.

(i) Sulfondiethylmethane.

(j) Sulfonethylmethane.

(k) Sulfonmethane.

(l) Tiletamine and zolazapam or any salt thereof.

(3) Any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomer is possible: Nalorphine.

(4) **Narcotic Drugs**. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(a) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(b) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(c) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(d) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active non-narcotic ingredients in recognized therapeutic amounts.

(e) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active non-narcotic ingredients in recognized therapeutic amounts.

(f) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(g) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active non-narcotic ingredients in recognized therapeutic amounts.

(h) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active non-narcotic ingredients in recognized therapeutic amounts.

(5) **Anabolic Substances**. Any quantity of the following substances or its isomer, ester, salt, or derivative except that anabolic substances in a dosage form approved by the Food and Drug Administration for administration through implants to cattle or other nonhuman species shall not be classified as controlled substances:

(a) Boldenone;

(b) Chlorotestosterone (4-chlortestosterone);

(c) Clostebol;

(d) Dehydrochlormethyltestosterone;

(e) Dihydrotestosterone (4-dihydrotestosterone);

(f) Dostanolone;

(g) Ethylestrenol;

(h) Fluoxymesterone;

(i) Formebulone (formebolone);

(j) Human growth hormone;

(k) Mesterolone;

(l) Methandienone;

(m) Methandranone;

(n) Methandriol;

(o) Methandrostenolone;

(p) Methenolone;

(q) Methyltestosterone;

(r) Milbolerone;

(s) Nandrolone;

(t) Norethandrolone;

(u) Oxandrolone;

(v) Oxymesterone;

(w) Oxymetholone;

(x) Stanolone;

(y) Stanozolol;

(z) Testolactone;

(aa) Testosterone;

(bb) Trenbolone.

(6) Hallucinogenic Substances: Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, its salts, isomer, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U. S. Food and Drug Administration approved drug product.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

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

**855-080-0024**
**Schedule IV**

(1) **Schedule IV** consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in this rule.

(2) **Depressants**. Unless specifically excepted or listed in another schedule, any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Alprazolam;

(b) Barbital;
(c) Bromazepam;
(d) Butorphanol;
(e) Camazepam;
(f) Carisoprodol;
(g) Chloral betaine;
(h) Chloral hydrate;
(i) Chlordiazepoxide;
(j) Clobazam;
(k) Clonazepam;
(l) Clorazepate;
(m) Clotiazepam;
(n) Cloxazolam;
(o) Delorazepam;
(p) Diazepam;
(q) Estazolam;
(r) Ethclorvynol;
(s) Ethinamate;
(t) Ethyl loflazepate;
(u) Fludiazepam;
(v) Flunitrazepam;
(w) Flurazepam;
(x) Halazepam;
(y) Haloxazolam;
(z) Ketazolam;
(aa) Loprazolam;
(bb) Lorazepam;
(cc) Lormetazepam;
(dd) Mebutamate;
(ee) Medazepam;
(ff) Meprobamate;
(gg) Methohexital;
(hh) Methylphenobarbital (mephobarbital);
(ii) Midazolam;
(jj) Nimetazepam;
(kk) Nitrazepam;
(ll) Nordiazepam;
(mm) Oxazepam;
(nn) Oxazolam;
(oo) Paraldehyde;
(pp) Petrichloral;
(qq) Phenobarbital;
(rr) Pinazepam;
(ss) Prazepam;
(tt) Quazepam;
(uu) Temazepam;
(vv) Tetrazepam;
(ww) Triazolam;
(xx) Zolpidem.

(3) **Fenfluramine**. Any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Fenfluramine.

(4) **Stimulants**. Unless specifically excepted or listed in another schedule, any quantity of the following substances, including its salts, isomers and salts of isomers:
(a) Cathine;
(b) Diethylpropion;
(c) Fencamfamin;
(d) Fenproporex;
(e) Mazindol;
(f) Mefenorex;
(g) Pemoline (including organometallic complexes and chelates thereof);
(h) Phentermine;
(i) Pipradrol;
(j) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(5) **Other substances**. Unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including its salts: Pentazocine.

Stat. Auth.: ORS 475.035
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

**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 this rule:

(1) *Narcotic drugs*. Unless specifically excepted or unless listed in another schedule, any of the following substance and its salts: Buprenorphine.

(2) *Narcotic drugs containing non-narcotic active medicinal ingredients*. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(a) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(b) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(c) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(d) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atrophine sulfate per dosage unit;

(e) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(f) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(3) *Stimulants*. Unless specifically excepted or listed in another schedule, any quantity of the following substances, including its salts, isomers and salts of isomers:
(a) Propylhexedrine;
(b) Pyrovalerone.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91

**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) Theophed;
(2) Guiaphed Elixir;
(3) Tedrigen Tablets;
(4) Choate's Leg Freeze;
(5) Tedral;
(6) Tedral Elixir;
(7) Tedral SA;
(8) Tedral Suspension;
(9) Asma-Ese;
(10) Asma-Aids;
(11) Benzedex;
(12) Bronkolixir;
(13) Bronkotabs;
(14) Vicks Inhaler;
(15) Primatine (P-Tablets);
(16) Estratest;
(17) Estratest HS
(18) Premarin with Methyltestosterone;
(19) Estradiol Cypionate Injection;
(20) Estradiol Valerate Injection.

Stat. Auth.: ORS 689.155 & ORS 689.205
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; 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

**Registration of Manufacturers, Distributors and Dispensers**

**855-080-0030**
**Definitions**

As used in OAR 855-080-0030 through 855-080-0095:

(1) "Act" means the same as in OAR 855-080-0015(1).

(2) "CFR" means **Code of Federal Regulations**.

(3) "Controlled premises" means:

(a) Places where original or other records or documents required under the Act are kept or required to be kept; and

(b) Places, including factories, warehouses, or other establishments, and conveyances, where persons registered under the Act may lawfully hold, manufacture, or distribute, administer, or dispense controlled substances.

(4) "Registration" or variants thereof means the annual registration required of manufacturers, distributors and dispensers of controlled substances under ORS 475.125 and "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, 21 U.S.C. 801 et seq.

(5) Terms not defined in this rule have the definition set forth in ORS 475.005.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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

**855-080-0031**
**Registration Requirements**

Manufacturers, distributors, and pharmacies (the latter referred to in OAR 855-080-0030 through 855-080-0095 as "dispensers") are required to register with the Board under the Act.

Stat. Auth.: ORS 475 & ORS 689
Stats. Implemented:
Hist.: 1PB 6-1982, f. & ef. 8-6-82

**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 & ORS 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 he is registered to manufacture, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by statute and rules for persons registered to distribute or dispense as applicable.

Stat. Auth.: ORS 475 & ORS 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

**855-080-0060**
**Inspections**

(1) The Board or its authorized representative may enter and shall be allowed entry to controlled premises to conduct administrative 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 Act, including, but not limited to, inventory and other records required to be kept pursuant to OAR 855-080-0070, order form records required to be kept under OAR 855-080-0075, distribution records required to be kept pursuant to OAR 855-080-0070, 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 controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Act;

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

(d) Collecting samples of controlled substances or ingredients;

(e) Checking of records and information on distribution of controlled substances by the registrants as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so, why);

(f) All other things appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act.

(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 Act and rules thereunder.

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

Stat. Auth.: ORS 475 & ORS 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

**855-080-0065**
**Security**

All applicants for registration and registrants shall, as applicable to the registration classification, comply with the security require-ments of **21 CFR 1301.02, 1301.71** through **1301.76** and **1301.90 through 1301.93**. The requirements of **21 CFR 1301.75** and **1301.76** relating to "practitioners" are applicable to applicants and registrants who are drug dispensers.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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; PB 5-1991, f. & cert. ef. 9-19-91

**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; 21 CFR 1304.02** through **1304.19; 1304.21** through **1304.29; 1304.31** through **1304.38**; except that an inventory of all controlled substances shall be taken by registrants every year on the same date as the biennial inventory required by **CFR 1304.13**. All such records shall be maintained for a period of three years.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475.035 & ORS 689.205
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; 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

**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 **1305.16**.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 475 & ORS 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

**855-080-0080**
**Special Exceptions**

The provisions of **21 CFR 1307.11 through 1307.15** are applicable under the Act.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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

## 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 **1306.26** and **1304.03(d)** shall be complied with the registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling dispensing, recordkeeping and filing of prescriptions for controlled substances.

(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 **1306.25** 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**.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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; PB 15-1989, f. & cert. ef. 12-26-89; PB 5-1991, f. & cert. ef. 9-19-91

**855-080-0090**
**Inspections**

(1) The Board or its authorized representative may enter and shall be allowed entry to controlled premises to conduct administrative inspections at the times, in the manner and for the purposes described in OAR 855-080-0060(1), as may be applicable to the requirements under OAR 855-080-0085.

(2) Such inspections may be conducted in connection with applications for initial or renewal pharmacy or pharmacist license or registration, during routine inspections of pharmacies or at any time the Board or its representative determines that there is reasonable basis for concluding that inspection is necessitated in order to ensure that there is compliance with the Act.

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

Stat. Auth.: ORS 475 & ORS 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

**855-080-0095**
**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 secretary.

Stat. Auth.: ORS 475
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78

**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 registration 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.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]
Stat. Auth.: ORS 475 & ORS 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

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 Drug Enforcement Administration and to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.

[Publications: The publication(s) referred to or incorporated by reference in this rule are available from the agency.]

Stat. Auth.: ORS 475.035 & ORS 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

## 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

**855-110-0005**
**Fees for Examinations, Intern/Pharmacist Licenses Technician Registration**

(1) Pharmacist license examination (NAPLEX) and re-examination fee — $300.

(2) Pharmacist jurisprudence re-examination fee — $25.

(3) Pharmacist licensing by reciprocity fee — $200.

(4) Pharmacist licensing by score transfer fee — $200.

(5) Intern License fee. Expires May 31 triennially — $30.

(6) Pharmacist license fee. Expires June 30 annually — $75. Delinquent renewal fee — $50.

(7) Certification of approved providers of continuing education courses fee, none at this time.

(8) Technician registration fee. Expires September 30 annually — $25.Delinquent renewal fee — $20.

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 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

**855-110-0007**
**Fees for Registration, Renewal, and Reinspection of Drug Outlets**

(1) County Health Clinic. Expires March 31 annually — $75. Delinquent renewal fee — $25.

(2) Drug room fee. Expires March 31 annually — $75. Delinquent renewal fee — $75.

(3) Manufacturer. Expires September 30 annually — $225. Delinquent renewal fee — $100.

(4) Medicinal Gas Class C. Expires January 31 annually — $50. Delinquent renewal fee — $25.

(5) Nonprescription Class A. Expires January 31 annually — $50. Delinquent renewal fee — $25.

(6) Nonprescription Class B. Expires January 31 annually — $25. Delinquent renewal fee — $10.

(7) Nonprescription Class D. Expires January 31 annually — $100. Delinquent renewal fee — $25.

(8) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer — $50. Expires December 31 annually.

(9) Reinspection fee — $100. Applies to any reinspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(10) Retail or Institutional Drug Outlet. Expires March 31 annually — $100. Delinquent renewal fee — $75.

(11) Student Health Center. Expires March 31 annually — $75. Delinquent renewal fee — $25.

(12) Veterinary Drug Outlet, Expires September 30 annually — $00. Delinquent renewal fee — $00

(13) Wholesaler. Expires September 30 annually — $225. Delinquent renewal fee — $100.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.135

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

**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 Clinics controlled substance registration fee, $25 annually.

(3) Drug Room controlled substance registration fee, $25 annually.

(4) Manufacturers controlled substance registration fee, $50 annually.

(5) Retail or Institutional Drug Outlet controlled substance registration fee, $25 annually.

(6) Schedule II Precursor Registration fee, $25 annually.

(7) Wholesalers controlled substance registration fee, $50 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

**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.

(2) All fees and charges must be paid before public records will be available for inspection or copies provided.

(3) The Board establishes the following fees:

(a) Photocopying: First page copied $1; Each additional page 25 cents;

(b) Photocopying: If research is necessary/per hour $60 minimum charge $15;

(c) Computer list/pharmacist or pharmacy/per set $75;

(d) Labels (Peel-'n'-stick)/pharmacist or pharmacy: Per set $80;

(e) Computer disk/pharmacists or pharmacy: Per disk $80;

(f) Minutes/per year $35;

(g) Individual Board meeting minutes/per month $5;

(h) Cassette tape recordings: Two sides $9. One side $6. Portions of sides one and two $9;

(i) Statutes and Rules/per set $15. Statutes only $5. Rules only. $10;

(j) Poison Register/each $10;

(k) Grade Certification/each $10;

(l) Pharmacist Wall Certificate, duplicate $15.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.135

Hist.: PB 10-1990, f. & cert. ef. 12-5-90; PB 1-1996, f. & cert. ef. 4-5-96