Oregon Board of Pharmacy
Laws & Rules

Oregon Revised Statute Chapter 475
Oregon Revised Statute Chapter 689
Oregon Administrative Rules Chapter 855

As filed through January 15, 2017

For all rule changes filed after January 15, 2017 - please see our website at www.pharmacy.state.or.us

Chapter 475 — Controlled Substances; Illegal Drug Cleanup; Paraphernalia; Precursors

Chapter 475 — Controlled Substances; Illegal Drug Cleanup; Paraphernalia; Precursors 1

UNIFORM CONTROLLED SUBSTANCES ACT 1

(Generally) 1

475.005 Definitions for ORS 475.005 to 475.285 and 475.752 to 475.980. 1

475.035 Authority to control schedule; rules. 3

475.055 Publishing of schedules. 4

475.059 Classification of marijuana. 4

475.065 Classification of methamphetamine; exceptions 4

475.095 Rules; fees. 4

475.100 4

475.101 Immunity for reporting violation 4

(Registration) 5

475.125 Registration requirements 5

475.135 Grounds to grant or deny registration; scope of registration; effect of federal registration. 5

475.145 Revocation and suspension of registration. 6

475.155 Order to show cause. 7

475.165 Records of registrants 7

(Records) 7

475.175 When order forms required. 7

475.185 When prescriptions required. 7

475.188 Prescription drug orders; electronic transmission. 8

475.190 Exception to prescription requirement; rules. 9

(Miscellaneous) 9

475.215 Cooperative arrangements. 9

475.225 Education and research. 10

(Enforcement) 10

475.235 Burden of proof; status of analysis of controlled substance; notice of objection. 10

475.245 Conditional discharge. 11

475.255 Status of penalties. 12

475.265 When prosecution barred. 12

(Interpretation; Title) 12

475.275 Uniformity of interpretation. 12

475.285 Short title 12

475.290 Applicability of Uniform Controlled Substances Act to marijuana. 12

OREGON MEDICAL MARIJUANA ACT 12

475.324 Limits on confiscation of marijuana 14

ILLEGAL DRUG CLEANUP 14
475.405 Definitions for ORS 475.405 to 475.495 14
475.415 Request for cleanup. 15
475.425 Environmental Quality Commission rules; designation of chemicals. 15
475.435 Authority of director. 15
475.445 Site entry; purposes. 16
475.455 Liability of certain persons for cleanup costs. 16
475.465 Liability of state for cleanup. 18
475.475 Department record of costs; collection of costs. 18
475.485 Costs and penalties as lien; enforcement of lien. 18
475.495 Illegal Drug Cleanup Fund; sources; uses. 19
DRUG PARAPHERNALIA 20
475.525 Sale of drug paraphernalia prohibited; definition of drug paraphernalia; exceptions. 20
475.535 Action to enforce ORS 475.525 to 475.565. 21
475.545 Order of forfeiture of paraphernalia; effect. 21
475.555 Seizure of drug paraphernalia. 21
475.565 Civil penalty for violation of ORS 475.525. 22
475.744 Providing hypodermic device to minor prohibited; exception. 23
PENALTIES 23
475.752 Prohibited acts generally; penalties; exceptions; affirmative defense for certain peyote uses; causing death by Schedule IV substance. 23
475.754 Affirmative defense to unlawfully possessing pseudoephedrine. 25
475.806 Unlawful manufacture of hydrocodone. 25
475.808 Unlawful manufacture of hydrocodone within 1,000 feet of school. 25
475.810 Unlawful delivery of hydrocodone. 25
475.812 Unlawful delivery of hydrocodone within 1,000 feet of school. 25
475.814 Unlawful possession of hydrocodone. 25
475.816 Unlawful manufacture of methadone. 26
475.818 Unlawful manufacture of methadone within 1,000 feet of school. 26
475.820 Unlawful delivery of methadone. 26
475.822 Unlawful delivery of methadone within 1,000 feet of school. 26
475.824 Unlawful possession of methadone. 26
475.826 Unlawful manufacture of oxycodone. 26
475.828 Unlawful manufacture of oxycodone within 1,000 feet of school. 26
475.830 Unlawful delivery of oxycodone. 26
475.832 Unlawful delivery of oxycodone within 1,000 feet of school. 26
475.834 Unlawful possession of oxycodone. 27
475.846 Unlawful manufacture of heroin. 27
475.848 Unlawful manufacture of heroin within 1,000 feet of school. 27

475.850 Unlawful delivery of heroin. 27
475.852 Unlawful delivery of heroin within 1,000 feet of school. 27
475.854 Unlawful possession of heroin. 27
475.856 Unlawful manufacture of marijuana; exceptions. 27
475.858 Unlawful manufacture of marijuana within 1,000 feet of school; exceptions. 28
475.860 Unlawful delivery of marijuana; exceptions. 28
475.862 Unlawful delivery of marijuana within 1,000 feet of school; exceptions. 28
475.864 Unlawful possession of marijuana or marijuana product; exceptions. 28
475.866 Unlawful manufacture of 3,4-methylenedioxymethamphetamine. 29
475.868 Unlawful manufacture of 3,4-methylenedioxymethamphetamine within 1,000 feet of school. 29
475.870 Unlawful delivery of 3,4-methylenedioxymethamphetamine. 30
475.872 Unlawful delivery of 3,4-methylenedioxymethamphetamine within 1,000 feet of school. 30
475.874 Unlawful possession of 3,4-methylenedioxymethamphetamine. 30
475.876 Unlawful manufacture of cocaine. 30
475.878 Unlawful manufacture of cocaine within 1,000 feet of school. 30
475.880 Unlawful delivery of cocaine. 30
475.882 Unlawful delivery of cocaine within 1,000 feet of school. 30
475.884 Unlawful possession of cocaine. 30
475.886 Unlawful manufacture of methamphetamine. 31
475.888 Unlawful manufacture of methamphetamine within 1,000 feet of school. 31
475.890 Unlawful delivery of methamphetamine. 31
475.892 Unlawful delivery of methamphetamine within 1,000 feet of school. 31
475.894 Unlawful possession of methamphetamine. 31
475.898 Immunity from drug-related offenses for emergency medical assistance. 31
475.900 Crime category classification; proof of commercial drug offense. 33
475.902 Directives to Oregon Criminal Justice Commission. 35
475.904 Unlawful manufacture or delivery of controlled substance within 1,000 feet of school; exceptions. 35
475.906 Penalties for unlawful delivery to minors. 36
475.907 Sentencing for unlawful delivery of cocaine, methamphetamine, heroin or ecstasy to minors. 36
475.908 Causing another person to ingest a controlled substance. 36
475.910 Application of controlled substance to the body of another person; prohibition. 37
475.912 Unlawful delivery of imitation controlled substance. 37
475.914 Prohibited acts for registrants; penalties. 37
475.916 Prohibited acts involving records and fraud; penalties. 38
475.918 Falsifying drug test results. 38
475.920 Providing drug test falsification equipment. 38

475.924 Definitions for ORS 164.061, 475.907, 475.924 and 475.925 38
475.925 Sentences for certain controlled substance offenses. 39
475.930 Imposition of sentence under ORS 164.061, 475.907, 475.924 and 475.925. 39
475.934 Sentencing of persons with previous conviction for controlled substance offense 40
475.935 Presumptive sentences for certain methamphetamine offenses. 41
PRECURSOR SUBSTANCES 42
475.940 Precursor substances described 42
475.945 Authority and duties of Department of State Police; rules. 43
475.947 Warning notice for precursor substance violation. 44
475.949 Injunctive relief for precursor substance violation. 44
475.950 Failure to report precursor substances transaction. 44
475.955 Failure to report missing precursor substances. 45
475.960 Illegally selling drug equipment. 46
475.962 Distribution of equipment, solvent, reagent or precursor substance with intent to facilitate manufacture of controlled substance. 46
475.965 Providing false information on precursor substances report or record. 46
475.967 Possession of precursor substance with intent to manufacture controlled substance. 46
475.969 Unlawful possession of phosphorus. 46
475.971 Unlawful possession of anhydrous ammonia. 47
475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records 47
475.975 Unlawful possession of iodine in its elemental form; recording transfers; unlawful distribution of iodine in its elemental form. 48
475.976 Unlawful possession of iodine matrix; recording transfers; unlawful distribution of iodine matrix. 48
475.977 Possessing or disposing of methamphetamine manufacturing waste. 49
475.978 Methyl sulfonyl methane; transfers; records; rules. 50
475.979 Unlawful possession of lithium metal or sodium metal. 50
475.980 Affirmative defense to ORS 475.969, 475.971, 475.975 (1) and 475.976 (1). 51
Chapter 689 — Pharmacists; Drug Outlets; Drug Sales, Occupations and Professions 53
689.005 Definitions 53
689.025 Policy; purpose. 56
689.035 Short title 57
689.045 Severability 57
STATE BOARD OF PHARMACY 57
689.115 Membership; qualifications; term; vacancy; compensation. 57
689.135 General powers of board; fees 59

689.139 State Board of Pharmacy Account; disposition of receipts. 61
689.145 Enforcement powers of board. 61
689.151 Board control over licensing, standards and discipline. 61
689.153 Continuing authority of board upon lapse, suspension, revocation or voluntary surrender of license or certificate. 61
689.155 Authority of board over medications, drugs, devices and other materials; rules. 62
689.165 Officers; executive director. 62
689.175 Compensation of board members and executive director. 63
689.185 Meetings. 63
689.195 Employees. 63
689.205 Rules. 64
689.207 Authority of board to require fingerprints. 64
PRACTICE OF PHARMACY 64
689.225 License requirement; exceptions; possession of drugs; regulation of pharmacy technicians; rules; penalty. 64
689.255 Qualifications for licensure by examination. 65
689.265 Qualifications for licensure by reciprocity. 66
689.275 Renewal of licenses; rules; fees. 66
689.285 Continuing pharmacy education; rules; fees. 67
689.295 Practice of clinical pharmacy. 68
REGULATION OF DRUG OUTLETS 68
689.305 Registration of drug outlets; rules. 68
689.315 Application; rules. 68
689.325 Required reports. 69
689.335 Certificate required; reinstatement. 69
DISCIPLINE 70
689.405 Grounds for discipline; investigation; procedure as contested case. 70
689.445 Penalties and reinstatement. 71
689.455 Duty to report suspected violations and prohibited conduct; liability for reporting; confidentiality of report. 72
PHARMACY TECHNICIANS 72
689.486 When license required; qualifications for licensure; renewal; supervision required. 72
689.490 Board to establish licensing system; rules; fees. 73
689.495 Provision of licensing information. 73
689.497 Report required upon termination of pharmacy technician. 74
689.499 Pharmacy technician specialized education program; rules. 74
REQUIREMENTS RELATING TO SALES 74
689.505 Labeling requirements; rules. 74
689.508 Prescription records. 76

689.515 Regulation of generic drugs; substitutions; rules. 76
689.522 Substitution of biosimilar products for prescribed biological products. 78
689.525 Out-of-state prescriptions. 78
689.527 Prohibited practices; rules. 78
689.532 Complimentary samples. 79
689.555 Agricultural drugs, nonprescription drugs and certain other substances. 79
689.557 Disposal of marijuana at retail drug outlets; rules; exemption from criminal liability. 80
MISCELLANEOUS 80
689.605 Power to dispense drugs from hospital pharmacies, drug rooms and penal institutions; rules. 80
689.615 Display of certificate or license; rules. 81
689.635 Dispensing according to naturopathic formulary; effect of filling prescription of naturopath 82
689.645 Power to administer and prescribe vaccines, provide approved patient care services; rules. 82
689.655 Power to administer drugs and devices; rules. 83
689.661 Power to perform tests and examinations related to federally cleared analytes. 83
689.681 Opiate overdose; treatments; training; administration of naloxone; rules. 83
689.683 Prescription and dispensation of certain contraceptives; rules; insurance coverage. . 84
CHARITABLE PRESCRIPTION DRUG PROGRAM 87
689.770 Definitions for ORS 689.770 to 689.780. 87
689.772 Establishment of program; immunity from liability; rules. 87
689.774 Rules. 88
689.776 Inspection; audit. 88
689.778 Eligibility. 88
689.780 Immunity. 88
PENALTIES 89
689.832 Civil penalties. 89
689.854 Civil penalty for violation of ORS 689.515 90
689.995 Criminal penalties. 90

Chapter 475 — Controlled Substances; Illegal Drug Cleanup; Paraphernalia; Precursors

2015 EDITION

UNIFORM CONTROLLED SUBSTANCES ACT

(Generally)

475.005 Definitions for ORS 475.005 to 475.285 and 475.752 to 475.980. As used in ORS 475.005 to 475.285 and 475.752 to 475.980, unless the context requires otherwise:

(1) "Abuse" means the repetitive excessive use of a drug short of dependence, without legal or medical supervision, which may have a detrimental effect on the individual or society.

(2) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(a) A practitioner or an authorized agent thereof; or

(b) The patient or research subject at the direction of the practitioner.

(3) "Administration" means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(4) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(5) "Board" means the State Board of Pharmacy.

(6) "Controlled substance":

(a) Means a drug or its immediate precursor classified in Schedules I through V under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, as modified under ORS 475.035. The use of the term "precursor" in this paragraph does not control and is not controlled by the use of the term "precursor" in ORS 475.752 to 475.980.

(b) Does not mean industrial hemp, as defined in ORS 571.300, or industrial hemp commodities or products.

(7) "Counterfeit substance" means a controlled substance or its container or labeling, which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, delivered or dispensed the substance.

(8) "Deliver" or "delivery" means the actual, constructive or attempted transfer, other than by administering or dispensing, from one person to another of a controlled substance, whether or not there is an agency relationship.

(9) "Device" means instruments, apparatus or contrivances, including their components, parts or accessories, intended:

(a) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals; or

(b) To affect the structure of any function of the body of humans or animals.

(10) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, and includes the prescribing,

administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

(11) “Dispenser” means a practitioner who dispenses.

(12) “Distributor” means a person who delivers.

(13) “Drug” means:

(a) Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of humans or animals; and

(d) Substances intended for use as a component of any article specified in paragraph (a), (b) or (c) of this subsection; however, the term does not include devices or their components, parts or accessories.

(14) “Electronically transmitted” or “electronic transmission” means a communication sent or received through technological apparatuses, including computer terminals or other equipment or mechanisms linked by telephone or microwave relays, or any similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

(15) “Manufacture” means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance:

(a) By a practitioner as an incident to administering or dispensing of a controlled substance in the course of professional practice; or

(b) By a practitioner, or by an authorized agent under the practitioner’s supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

(16) “Marijuana”:

(a) Except as provided in this subsection, means all parts of the plant Cannabis family Moraceae, whether growing or not; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its resin.

(b) Does not mean the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

(c) Does not mean industrial hemp, as defined in ORS 571.300, or industrial hemp commodities or products.

(17) “Person” includes a government subdivision or agency, business trust, estate, trust or any other legal entity.

(18) “Practitioner” means physician, dentist, veterinarian, scientific investigator, certified nurse practitioner, physician assistant or other person licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state but does not include a pharmacist or a pharmacy.

(19) “Prescription” means a written, oral or electronically transmitted direction, given by a practitioner for the preparation and use of a drug. When the context requires, “prescription” also means the drug prepared under such written, oral or electronically transmitted direction. Any

label affixed to a drug prepared under written, oral or electronically transmitted direction shall prominently display a warning that the removal thereof is prohibited by law.

(20) "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

(21) "Research" means an activity conducted by the person registered with the federal Drug Enforcement Administration pursuant to a protocol approved by the United States Food and Drug Administration.

(22) "Ultimate user" means a person who lawfully possesses a controlled substance for the use of the person or for the use of a member of the household of the person or for administering to an animal owned by the person or by a member of the household of the person.

(23) "Within 1,000 feet" means a straight line measurement in a radius extending for 1,000 feet or less in every direction from a specified location or from any point on the boundary line of a specified unit of property. [1977 c.745 §1; 1979 c.777 §49; 1979 c.785 §5; 1981 c.220 §1; 1981 c.666 §1; 1987 c.657 §8; 1995 c.440 §22; 2001 c.615 §15; 2001 c.623 §3; 2009 c.897 §4; 2013 c.588 §1]

475.010 [Amended by 1953 c.342 §3; 1957 c.587 §6; 1965 c.545 §1; 1971 c.743 §378; 1973 c.697 §9; 1974 c.67 §5; repealed by 1977 c.745 §54]
475.015 [1977 c.745 §3; 1979 c.777 §50; repealed by 1981 c.666 §11]
475.020 [Repealed by 1957 c.587 §12]
475.025 [1977 c.745 §4; repealed by 1981 c.666 §11]
475.030 [Repealed by 1957 c.587 §12]

475.035 Authority to control schedule; rules. (1) In arriving at any decision on changes in or addition to classification when changes or additions are proposed by the federal Drug Enforcement Administration or by any other reliable source, the State Board of Pharmacy shall review the scientific knowledge available regarding the substance, its pharmacological effects, patterns of use and misuse, and potential consequences of abuse, and consider the judgment of individuals with training and experience with the substance.

(2) Whenever the board determines that a change in or an addition to the schedule of a controlled substance is justified, the board by rule may order the change and fix the effective date thereof.

(3) If a substance is an ingredient of a controlled substance, the ingredient shall be considered to be in the same schedule as that controlled substance. Substances which are precursors of the ingredient shall not be subject to control solely because they are precursors of the ingredient. The use of the term "precursor" in this subsection does not control and is not controlled by the use of the term "precursor" in ORS 475.752 to 475.980.

(4) The board shall administer ORS 475.005 to 475.285 and 475.752 to 475.980 in accordance with ORS chapter 183.

(5) Authority to control under this section does not extend to tobacco or to alcoholic beverages as defined in ORS 471.001. [1977 c.745 §5; 1981 c.666 §2; 1987 c.657 §9; 1995 c.301 §31; 1995 c.440 §23; 2001 c.615 §16]

475.040 [Repealed by 1957 c.587 §12]
475.045 [1977 c.745 §7a; repealed by 2011 c.524 §4]
475.050 [Repealed by 1957 c.587 §12]

475.055 Publishing of schedules. The State Board of Pharmacy shall publish the classification of controlled substances within 30 days following revision of any classification or reclassification of a controlled substance. [1977 c.745 §6; 1981 c.666 §3]

475.059 Classification of marijuana. The State Board of Pharmacy shall classify marijuana as a controlled substance in Schedule II, III, IV or V. [2009 c.898 §2]

Note: 475.059 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.060 [Repealed by 1957 c.587 §12]

475.065 Classification of methamphetamine; exceptions. (1) The State Board of Pharmacy shall classify methamphetamine as a controlled substance in Schedule I.

(2) Notwithstanding subsection (1) of this section, methamphetamine, its salts, isomers and salts of its isomers shall be classified as a controlled substance in Schedule II for purposes of currently accepted medical use in treatment in the United States and currently accepted medical use with severe restrictions within the meaning of 21 U.S.C. 812(b)(2). [2009 c.898 §3]

Note: 475.065 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.070 [Amended by 1961 c.648 §12; repealed by 1971 c.743 §432]
475.075 [1977 c.745 §2; 1979 c.777 §51; repealed by 1981 c.666 §11]
475.080 [Repealed by 1959 c.411 §22]
475.085 [1977 c.745 §55; 1979 c.777 §52; repealed by 1981 c.666 §11]
475.090 [Amended by 1953 c.543 §3; 1957 c.587 §7; repealed by 1971 c.743 §432]

475.095 Rules; fees. The State Board of Pharmacy may adopt rules relating to fees and charge reasonable fees in addition to any other fees required by statute or rule, relating to the registration and control of the manufacture, delivery and dispensing of controlled substances within this state. [1977 c.745 §7; 1981 c.666 §4]

475.100 [Amended by 1953 c.396 §2; 1957 c.587 §8; 1963 c.229 §1; 1965 c.15 §1; 1965 c.545 §2; 1971 c.743 §379; repealed by 1977 c.745 §54]

475.101 Immunity for reporting violation. A person who, in good faith, makes a report of a violation of ORS 475.752 to 475.980 and who has reasonable grounds for making the report is immune from any civil or criminal liability that might otherwise be incurred or imposed with respect to making the report or to the content of the report. The person has the same immunity with respect to participating in a judicial proceeding resulting from the report. [2005 c.706 §7]
Note: 475.101 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.110 [Amended by 1953 c.396 §2; 1965 c.545 §3; 1971 c.743 §379a; repealed by 1977 c.745 §54]
475.120 [Repealed by 1971 c.743 §432]

(Registration)

475.125 Registration requirements. (1) Every person who manufactures, delivers or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within this state, must obtain annually a registration issued by the State Board of Pharmacy in accordance with its rules.

(2) Persons registered by the board under ORS 475.005 to 475.285 and 475.752 to 475.980 to manufacture, deliver, dispense or conduct research with controlled substances may possess, manufacture, deliver, dispense or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of ORS 475.095 and 475.125 to 475.185 and other applicable laws of this state.

(3) The following persons need not register and may lawfully possess controlled substances under ORS 475.005 to 475.285 and 475.752 to 475.980:

(a) An agent or employee of any registered manufacturer, distributor or dispenser of any controlled substance if the agent or employee is acting in the usual course of business or employment.

(b) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.

(c) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance, unless otherwise prohibited.

(d) A practitioner otherwise licensed under the laws of this state and authorized to dispense or administer a controlled substance by the licensing authority.

(4) The board may waive by rule the requirement for registration of certain manufacturers or dispensers if it finds it consistent with the public health and safety.

(5) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, delivers or dispenses controlled substances.

(6) The board may inspect the establishment of a registrant or applicant for registration in accordance with the rules of the board. [1977 c.745 §8; 1995 c.440 §24; 2011 c.524 §23]

475.130 [Repealed by 1957 c.587 §12]

475.135 Grounds to grant or deny registration; scope of registration; effect of federal registration. (1) The State Board of Pharmacy shall register or renew the registration of an applicant to manufacture or dispense controlled substances included in schedules under procedures defined in ORS 475.035, unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider the following factors:

(a) Failure to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels;

(b) Failure to comply with applicable state or local laws;

(c) Any convictions of the applicant under any federal or state laws relating to any controlled substance;

(d) Past experience in the manufacture, delivery or dispensing of controlled substances and the existence in the applicant's establishment of effective controls against diversion;

(e) Furnishing by the applicant of false or fraudulent material in any application filed under ORS 475.005 to 475.285 and 475.752 to 475.980;

(f) Suspension or revocation of the applicant's federal registration to manufacture, deliver or dispense controlled substances as authorized by federal law; or

(g) Any other factors relevant to and consistent with the public health and safety.

(2) Registration under subsection (1) of this section does not entitle a registrant to manufacture, deliver or dispense controlled substances in Schedule I or II other than those specified in the registration.

(3) Practitioners must be registered to conduct research with controlled substances in Schedules I through V if they are authorized to conduct research under the law of this state. The board need not require separate registration under ORS 475.095 and 475.125 to 475.185 for practitioners engaging in research with controlled substances in Schedules I through V where the registrant is already registered under ORS 475.095 and 475.125 to 475.185 in another capacity. Persons with valid registration from the Drug Enforcement Administration for research on controlled substances may conduct research within this state in compliance with other state law upon furnishing the board evidence of that federal registration, and are exempt from state prosecution for possession and distribution of controlled substances to the extent of the registration. Registration under ORS 475.005 to 475.285 and 475.752 to 475.980 does not exempt the registrant from compliance with any other relevant law of this state or the United States, unless such exemption is expressly provided under ORS 475.005 to 475.285 and 475.752 to 475.980.

(4) Notwithstanding this section, the manufacture, delivery or dispensing of any controlled substance excluded from any medical use by federal law is prohibited, except:

(a) For research authorized under subsection (3) of this section and ORS 475.225; or

(b) As otherwise provided by state or federal law.

(5) Compliance by manufacturers and distributors with the provisions of the federal law respecting registration, excluding fees, entitles them to be registered under ORS 475.095 and 475.125 to 475.185. [1977 c.745 §9; 1979 c.777 §53; 1981 c.666 §5; 1995 c.440 §25; 2011 c.524 §24]

475.140 [Repealed by 1957 c.587 §12]

475.145 Revocation and suspension of registration. (1) A registration under ORS 475.135 to manufacture, deliver or dispense a controlled substance may be suspended or revoked by the State Board of Pharmacy upon a finding that:

(a) The registrant has furnished false or fraudulent material information in any application filed under ORS 475.005 to 475.285 and 475.752 to 475.980;

(b) The registrant has been convicted of a felony under any state or federal law relating to any controlled substance;

(c) The registrant has had the federal registration suspended or revoked to manufacture, deliver or dispense controlled substances;

(d) The registrant has violated any rule of the board under ORS 475.005 to 475.285 and 475.752 to 475.980;

(e) The registrant has failed to maintain proper records or has failed to follow proper refill procedures; or

(f) Continuance of registration would be inconsistent with the public interest under any factor stated in ORS 475.135.

(2) The board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

(3) If the board suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon

application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

(4) The board shall promptly notify the administration of all orders suspending or revoking registration and all forfeitures of controlled substances. [1977 c.745 §10; 1981 c.666 §6; 1995 c.440 §26]

475.150 [Amended by 1959 c.411 §1; 1971 c.418 §14; repealed by 1977 c.745 §54]

475.155 Order to show cause. (1) Before denying, suspending or revoking a registration, or refusing a renewal of registration, the State Board of Pharmacy shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked or suspended, or why the renewal should not be refused. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the board at a time and place not less than 30 days after the date of service of the order. These proceedings shall be conducted in accordance with ORS chapter 183 without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(2) The board may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under ORS 475.145 or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the board or dissolved by a court of competent jurisdiction. [1977 c.745 §11]

475.160 [Repealed by 1977 c.745 §54]

475.165 Records of registrants. Persons registered to manufacture, deliver or dispense controlled substances under ORS 475.005 to 475.285 and 475.752 to 475.980 shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and with any additional rules the State Board of Pharmacy issues. [1977 c.745 §12; 1995 c.440 §27]

(Records)

475.175 When order forms required. Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section. [1977 c.745 §13]

475.185 When prescriptions required. (1)(a) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance in Schedule II may not be dispensed without a written or electronically transmitted prescription of a practitioner.

(b) In emergency situations, as defined by rule of the State Board of Pharmacy, Schedule II drugs may be dispensed with an oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Such prescriptions shall be retained in conformity with the requirements of ORS 475.165.

(c) A prescription for a Schedule II substance may not be refilled.

(2) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedule III or IV may not be dispensed without a written, oral or electronically transmitted prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date on which it was issued and a prescription authorized to be refilled may not be refilled more than five times. Additional quantities of the controlled substances listed in Schedule III or IV may be authorized by a practitioner only through issuance of a new prescription.

(3) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedule V that is a prescription drug may not be dispensed without a written, oral or electronically transmitted prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date on which it was issued and a prescription authorized to be refilled may not be refilled more than five times. Additional quantities of the controlled substances listed in Schedule V may be authorized by a practitioner only through issuance of a new prescription.

(4) A controlled substance may not be delivered or dispensed other than for a medical purpose.

(5) Except in good faith and in the course of professional practice only, a practitioner or a pharmacist may not dispense controlled substances.

(6) Any oral or electronically transmitted prescription authorized by statute or rule must be stored by electronic means or reduced promptly to writing and filed by the pharmacy.

(7) Issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions or medication orders must be in conformance with the requirements of the federal law and rules of the board. [1977 c.745 §14; 1979 c.777 §54; 1981 c.666 §7; 2001 c.623 §4; 2011 c.524 §3; 2014 c.55 §1]

475.188 Prescription drug orders; electronic transmission. (1) Prescription drug orders may be transmitted by electronic means from a practitioner authorized to prescribe drugs directly to the dispensing pharmacist.

(2) All prescription drug orders communicated by way of electronic transmission shall:

(a) Be transmitted only by an authorized practitioner;

(b) Be transmitted directly to a pharmacist in a pharmacy of the patient's choice with no intervening person having access to the prescription drug order;

(c) Specify the prescribing practitioner's telephone number for verbal confirmation, the time and date of transmission, the identity of the pharmacy intended to receive the transmission and all other information required for a prescription by federal or state law; and

(d) Be traceable to the prescribing practitioner by an electronic signature or other secure method of validation.

(3) An electronic transmission of a prescription drug order shall be stored by electronic means or reduced promptly to writing, filed by the pharmacy and retained in conformity with the requirements of ORS 475.165.

(4) The dispensing pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of an electronically transmitted prescription drug order.

(5) All equipment for transmission, storage or receipt of electronically transmitted prescription drug orders shall be maintained to protect against unauthorized access.

(6) A pharmacist, pharmacy or pharmacy department shall not enter into an agreement with a practitioner or health care facility concerning the provision of any electronic transmission equipment or apparatus that would adversely affect a patient's freedom to select the pharmacy or pharmacy department of the patient's choice.

(7) A pharmacist, pharmacy or pharmacy department shall not provide any electronic equipment or apparatus to a practitioner or health care facility for the purpose of providing an incentive to the practitioner or health care facility to refer patients to a particular pharmacy or pharmacy department.

(8) There shall be no additional charge to the patient because the prescription drug order was electronically transmitted.

(9) Nothing in this section shall be construed as authorizing the electronic transmission of a prescription drug order when a written prescription is required under ORS 127.815, 137.473, 169.750 or 453.025. [2001 c.623 §2; 2003 c.102 §1; 2014 c.55 §2]

Note: 475.188 was added to and made a part of 475.005 to 475.285 by legislative action but was not added to any smaller series therein. See Preface to Oregon Revised Statutes for further explanation.

475.190 Exception to prescription requirement; rules. (1) Notwithstanding the provisions of ORS 475.185, upon registration with the State Board of Pharmacy, a humane society or animal control agency may purchase, possess and, subject to subsection (4) of this section, administer sodium pentobarbital to euthanize injured, sick, homeless or unwanted domestic pets and other animals.

(2) The State Board of Pharmacy, after consultation with the Oregon State Veterinary Medical Examining Board, shall adopt rules according to ORS 183.325 to 183.410 establishing requirements for registration, renewal of registration and revocation or suspension of registration under subsection (1) of this section. Those rules shall include a provision that the State Board of Pharmacy will suspend or revoke the registration of any humane society or animal control agency that allows a person who is not certified under subsection (4) of this section to administer sodium pentobarbital.

(3) Any person who is registered under ORS 475.005 to 475.285 and 475.752 to 475.980 to deliver or dispense controlled substances may deliver or dispense sodium pentobarbital to a humane society or animal control agency registered under subsections (1) and (2) of this section.

(4) The Oregon State Veterinary Medical Examining Board, after consultation with the State Board of Pharmacy, shall adopt rules establishing requirements for certification of persons to administer sodium pentobarbital. Those rules may require that a person complete certain educational or training programs in order to be certified. No person shall administer sodium pentobarbital unless the person is certified by the Oregon State Veterinary Medical Examining Board. [1983 c.342 §2; 1995 c.440 §28]

475.205 [1977 c.745 §24; repealed by 1981 c.666 §11]

(Miscellaneous)

475.215 Cooperative arrangements. The State Board of Pharmacy shall cooperate with federal and other state agencies in discharging its responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, it may:

(1) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances; and

(2) Cooperate in training programs concerning controlled substance law enforcement at local and state levels. [1977 c.745 §22]

475.225 Education and research. (1) The Oregon Health Authority shall carry out educational programs designed to prevent and deter misuse and abuse of controlled substances. In connection with these programs it may:

(a) Promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations;

(b) Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances;

(c) Consult with interested groups and organizations to aid them in solving administrative and organizational problems;

(d) Evaluate procedures, projects, techniques and controls conducted or proposed as part of educational programs on misuse or abuse of controlled substances;

(e) Disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat them; and

(f) Assist in the education and training of state and local law enforcement officials in their efforts to control misuse and abuse of controlled substances.

(2) The authority shall encourage research on the medical use, misuse and abuse of controlled substances. In connection with the research, and in furtherance of the enforcement of ORS 475.005 to 475.285 and 475.752 to 475.980, it may:

(a) Establish methods to assess accurately the physiological, psychological and social effects of controlled substances and identify their medical uses, relative hazard potential, and potential for abuse;

(b) Make studies and undertake programs of research to:

(A) Develop new or improved approaches, techniques, systems, equipment and devices to strengthen the enforcement of ORS 475.005 to 475.285 and 475.752 to 475.980;

(B) Determine patterns of use, misuse and abuse of controlled substances and the social effects thereof; and

(C) Improve methods for preventing, predicting, understanding and dealing with the misuse and abuse of controlled substances; or

(c) Enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations or special projects which bear directly on misuse and abuse of controlled substances.

(3) The authority may enter into contracts for educational and research activities without performance bonds and without regard to ORS 459A.475, 459A.480, 459A.485 and 459A.490. [1977 c.745 §25; 1981 c.666 §8; 1995 c.440 §29; 2003 c.794 §297; 2009 c.595 §963; 2015 c.167 §4]

(Enforcement)

475.235 Burden of proof; status of analysis of controlled substance; notice of objection. (1) It is not necessary for the state to negate any exemption or exception in ORS 475.005 to 475.285 and 475.752 to 475.980 in any complaint, information, indictment or other pleading or in any trial, hearing or other proceeding under ORS 475.005 to 475.285 and 475.752 to 475.980. The burden of proof of any exemption or exception is upon the person claiming it.

(2) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under ORS 475.005 to 475.285 and 475.752 to 475.980, the person is presumed not to be the holder of the registration or form. The burden of proof is upon the person to rebut the presumption.

(3)(a) When a controlled substance is at issue in a criminal proceeding before a grand jury, at a preliminary hearing, in a proceeding on a district attorney's information or for purposes of an early disposition program, it is prima facie evidence of the identity of the controlled substance if:

(A) A sample of the controlled substance is tested using a presumptive test for controlled substances;

(B) The test is conducted by a law enforcement officer trained to use the test or by a forensic scientist; and

(C) The test is positive for the particular controlled substance.

(b) When the identity of a controlled substance is established using a presumptive test for purposes of a criminal proceeding before a grand jury, a preliminary hearing, a proceeding on a district attorney's information or an early disposition program, the defendant, upon notice to the district attorney, may request that the controlled substance be sent to a state police forensic laboratory for analysis.

(4) Notwithstanding any other provision of law, in all prosecutions in which an analysis of a controlled substance or sample was conducted, a certified copy of the analytical report signed by the director of a state police forensic laboratory or the analyst or forensic scientist conducting the analysis shall be admitted as prima facie evidence of the results of the analytical findings unless the defendant has provided notice of an objection in accordance with subsection (5) of this section.

(5) If the defendant intends to object at trial to the admission of a certified copy of an analytical report as provided in subsection (4) of this section, not less than 15 days prior to trial the defendant shall file written notice of the objection with the court and serve a copy on the district attorney.

(6) As used in this section:

(a) "Analyst" means a person employed by the Department of State Police to conduct analysis in forensic laboratories established by the department under ORS 181A.150.

(b) "Presumptive test" includes, but is not limited to, chemical tests using Marquis reagent, Duquenois-Levine reagent, Scott reagent system or modified Chen's reagent. [1977 c.745 §23; 1989 c.194 §1; 1995 c.440 §6; 1997 c.346 §1; 2001 c.870 §14; 2003 c.538 §1; 2007 c.636 §§1,2; 2009 c.610 §8]

475.245 Conditional discharge. (1) Whenever any person pleads guilty to or is found guilty of an offense listed in subsection (5) of this section, the court, without entering a judgment of guilt and with the consent of the district attorney and the person, may defer further proceedings and place the person on probation.

(2) Upon violation of a term or condition of probation, the court may enter an adjudication of guilt and proceed as otherwise provided.

(3) Upon fulfillment of the terms and conditions of probation, the court shall discharge the person and dismiss the proceedings against the person. Discharge and dismissal under this section shall be without adjudication of guilt and is not a conviction for purposes of this section or for purposes of disqualifications or disabilities imposed by law upon conviction of a crime. There may be only one discharge and dismissal under this section with respect to any person.

(4) In the event that the period of probation under this section expires, but the terms and conditions of probation have not been fulfilled and no probation violation proceeding was initiated prior to the expiration of the period of probation, the court may not discharge the person and dismiss the proceedings against the person. The court shall instead issue an order requiring the person to appear and to show cause why the court should not enter an adjudication of guilt as described in subsection (2) of this section due to the failure of the person to fulfill the terms and conditions of probation prior to expiration of the period of probation. At the hearing on the order

to show cause, after considering any evidence or argument from the district attorney and the person, the court may:

(a) Order a new period of probation to allow the person to fulfill the terms and conditions of the previous period of probation; or

(b) Enter an adjudication of guilt as described in subsection (2) of this section.

(5) This section applies to the following offenses:

(a) Possession of a controlled substance under ORS 475.752 (3), 475.814, 475.824, 475.834, 475.854, 475.864, 475.874, 475.884 or 475.894;

(b) Unlawfully possessing a prescription drug under ORS 689.527 (6);

(c) Endangering the welfare of a minor under ORS 163.575 (1)(b);

(d) Frequenting a place where controlled substances are used under ORS 167.222; and

(e) A property offense that is motivated by a dependence on a controlled substance. [1977 c.745 §21; 1995 c.440 §30; 1999 c.799 §1; 2001 c.834 §§6,10; 2005 c.706 §26; 2005 c.708 §§56,57; 2011 c.524 §2; 2013 c.75 §1; 2015 c.125 §1]

475.255 Status of penalties. Any penalty imposed for violation of ORS 475.005 to 475.285 and 475.752 to 475.980 is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise authorized by law. [1977 c.745 §18; 1995 c.440 §31]

475.265 When prosecution barred. If a violation of ORS 475.005 to 475.285 and 475.752 to 475.980 is a violation of a federal law or the law of another state, a conviction or acquittal under federal law or the law of another state for the same act is a bar to prosecution in this state. [1977 c.745 §19; 1995 c.440 §32]

(Interpretation; Title)

475.275 Uniformity of interpretation. ORS 475.005 to 475.285 and 475.752 to 475.980 shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of ORS 475.005 to 475.285 and 475.752 to 475.980 among those states which enact similar laws. [1977 c.745 §28; 1995 c.440 §33]

475.285 Short title. ORS 475.005 to 475.285 and 475.752 to 475.980 may be cited as the Uniform Controlled Substances Act. [1977 c.745 §29; 1995 c.440 §7]

475.290 Applicability of Uniform Controlled Substances Act to marijuana. As used in the following statutes and any rule adopted under the following statutes, the term "controlled substance" does not include marijuana:

(1) ORS 475.125, 475.135, 475.145, 475.155 and 475.165.

(2) ORS 475.175, 475.185, 475.188 and 475.190. [2015 c.1 §72; 2015 c.614 §68]

475.295 [1989 c.1075 §2; 1991 c.460 §3; 1993 c.33 §358; renumbered 430.400 in 1993]

OREGON MEDICAL MARIJUANA ACT

Note: Amendments and additions to 475.300 to 475.346 (renumbered 475B.400 to 475B.525) become operative March 1, 2016. See sections 177 (2) and 179, chapter 614, Oregon Laws 2015. Refer to the 2013 Edition of Oregon Revised Statutes for the text of 475.300 to 475.346 that is operative until March 1, 2016.

Note: For the text of 475.309 (renumbered 475B.415) that is operative until March 1, 2016, see section 103, chapter 736, Oregon Laws 2015.

Note: For the text of 475.314 (renumbered 475B.450) that is operative until March 1, 2016, see section 5, chapter 79, Oregon Laws 2014.

475.300 [1999 c.4 §2; 2015 c.614 §90; renumbered 475B.400 in 2015]

475.302 [1999 c.4 §3; 2001 c.900 §205; 2003 c.14 §305; 2005 c.22 §346; 2005 c.822 §1; 2007 c.573 §1; 2009 c.595 §964; 2013 c.337 §1; 2013 c.726 §3; 2015 c.614 §80; 2015 c.844 §4; renumbered 475B.410 in 2015]

475.303 [2005 c.822 §7; 2009 c.595 §965; 2015 c.614 §90a; renumbered 475B.520 in 2015]

475.304 [2005 c.822 §8; 2007 c.573 §2; 2009 c.595 §966; 2011 c.630 §92; 2013 c.726 §4; 2015 c.614 §81; renumbered 475B.420 in 2015]

475.305 [1977 c.636 §1; 1979 c.674 §1; repealed by 1993 c.571 §30]

475.306 [1999 c.4 §7; 2005 c.822 §2; 2009 c.595 §967; 2015 c.614 §84; renumbered 475B.433 in 2015]

475.309 [1999 c.4 §4; 1999 c.825 §2; 2003 c.14 §306; 2005 c.822 §3; 2007 c.573 §3; 2009 c.595 §968; 2013 c.726 §5; 2015 c.736 §§103,116; renumbered 475B.415 in 2015]

475.312 [1999 c.4 §13; 2009 c.595 §969; 2015 c.614 §80b; renumbered 475B.418 in 2015]

475.314 [2013 c.726 §2; 2014 c.79 §5; 2015 c.614 §86; renumbered 475B.450 in 2015]

475.315 [1977 c.636 §2; 1979 c.674 §2; repealed by 1993 c.571 §30]

475.316 [1999 c.4 §5; 1999 c.825 §3; 2005 c.822 §13; 2007 c.573 §4; 2009 c.595 §970; 2015 c.614 §87b; renumbered 475B.478 in 2015]

475.319 [1999 c.4 §6; 1999 c.825 §4; 2005 c.22 §347; 2005 c.822 §12; 2015 c.614 §87a; renumbered 475B.480 in 2015]

475.320 [2005 c.822 §9; 2007 c.573 §5; 2009 c.595 §971; 2013 c.726 §6; 2015 c.614 §82; renumbered 475B.428 in 2015]

475.323 [1999 c.4 §8; 1999 c.825 §5; 2005 c.22 §348; 2013 c.726 §7; 2015 c.614 §90b; renumbered 475B.490 in 2015]
475.324 [2005 c.822 §10; repealed by 2015 c.614 §175a]

Note: 475.324 is repealed March 1, 2016. See sections 175a and 179, chapter 614, Oregon Laws 2015. 475.324 (2013 Edition) is set forth for the user's convenience.

475.324 Limits on confiscation of marijuana. A law enforcement officer who determines that a registry identification cardholder is in possession of amounts of usable marijuana or numbers of marijuana plants in excess of the amount or number authorized by ORS 475.320 may confiscate only any usable marijuana or plants that are in excess of the amount or number authorized.

475.325 [1977 c.636 §3; 1979 c.674 §3; repealed by 1993 c.571 §30]

475.326 [1999 c.4 §9; 2005 c.822 §11; 2015 c.614 §90c; renumbered 475B.483 in 2015]

475.328 [1999 c.4 §10; 2005 c.822 §4; 2015 c.614 §90d; renumbered 475B.485 in 2015]

475.331 [1999 c.4 §12; 2005 c.822 §5; 2009 c.595 §972; 2013 c.726 §8; 2015 c.614 §90e; renumbered 475B.460 in 2015]

475.334 [1999 c.4 §14; 2009 c.595 §973; 2015 c.614 §90f; renumbered 475B.517 in 2015]

475.335 [1977 c.636 §4; 1979 c.674 §4; repealed by 1993 c.571 §30]

475.338 [1999 c.4 §15; 2009 c.595 §974; 2015 c.614 §90g; renumbered 475B.525 in 2015]

475.340 [1999 c.4 §16; 2015 c.614 §90h; renumbered 475B.413 in 2015]

475.342 [1999 c.4 §11; 2015 c.614 §90i; renumbered 475B.515 in 2015]

475.345 [1977 c.636 §5; 1979 c.674 §5; repealed by 1993 c.571 §30]

475.346 [1999 c.4 §1; renumbered 475B.405 in 2015]

475.355 [1977 c.636 §6; 1979 c.674 §6; repealed by 1993 c.571 §30]

475.360 [1979 c.674 §10; repealed by 1993 c.571 §30]

475.365 [1977 c.636 §7; 1979 c.674 §7; repealed by 1993 c.571 §30]

475.375 [1977 c.636 §8; 1979 c.674 §8; repealed by 1993 c.571 §30]

ILLEGAL DRUG CLEANUP

475.405 Definitions for ORS 475.405 to 475.495. As used in ORS 475.405 to 475.495:

(1) "Chemical" means:

(a) Any material defined as a controlled substance or precursor substance as defined by ORS 475.005 to 475.285 and 475.744 to 475.980.

(b) Any substance used in the manufacture of a controlled substance as defined by ORS 475.005 to 475.285 and 475.744 to 475.980.

(c) Any material or substance designated by the Environmental Quality Commission under ORS 475.425.

(2) "Cleanup" includes any action the Department of Environmental Quality, or a person acting on behalf of the department, is required to take pursuant to a request under ORS 475.415.

(3) “Cleanup costs” means reasonable costs that are attributable to or associated with cleanup at an alleged illegal drug manufacturing site, including but not limited to the costs of administration, investigation, legal or enforcement activities, contracts and health studies.

(4) “Commission” means the Environmental Quality Commission.

(5) “Department” means the Department of Environmental Quality.

(6) “Director” means the Director of the Department of Environmental Quality.

(7) “Fund” means the Illegal Drug Cleanup Fund established under ORS 475.495.

(8) “Owner or operator” means any person who owns, leases, operates or controls an alleged illegal drug manufacturing site. “Owner or operator” does not include a person, who, without participating in the management of an alleged illegal drug manufacturing site, holds indicia of ownership primarily to protect a security interest in the site.

(9) “Site” means an illegal drug manufacturing site. [1987 c.699 §1; 1995 c.440 §8]

475.415 Request for cleanup. Upon the request of a law enforcement agency, the Department of Environmental Quality may identify, clean up, store and dispose of chemicals located at an alleged illegal drug manufacturing site. [1987 c.699 §2]

475.425 Environmental Quality Commission rules; designation of chemicals. (1) The Environmental Quality Commission shall consult with the law enforcement agencies in adopting rules necessary for the Department of Environmental Quality to carry out its responsibilities under ORS 475.415.

(2) By rule, the commission may designate as chemical for the purposes of ORS 475.405 to 475.495 any element, compound, mixture or solution that may be a controlled substance or precursor substance as defined by ORS 475.005 to 475.285 and 475.744 to 475.980 or used to illegally manufacture drugs. [1987 c.699 §3; 1995 c.440 §9]

475.435 Authority of director. (1) Upon request of a law enforcement agency, the Director of the Department of Environmental Quality:

(a) May undertake directly or by contract any cleanup action necessary to protect the public health, safety, welfare and the environment; or

(b) May authorize any person to carry out any cleanup action in accordance with any requirements of or directions from the director, if the director determines that the person will commence and complete the cleanup action properly and in a timely manner. However, the director in most circumstances shall not require the law enforcement agency to be responsible for carrying out the cleanup action.

(2) Nothing in ORS 475.415 to 475.455, 475.475 and 475.485 shall prevent the director from taking any emergency cleanup action necessary to protect public health, safety, welfare or the environment.

(3) The director may require a person liable under ORS 475.455 to conduct any cleanup action or related actions necessary to protect the public health, safety, welfare and the environment. The director’s action under this subsection may include but need not be limited to issuing an order specifying the cleanup action the person must take.

(4) The director may request the Attorney General to bring an action or proceeding for legal or equitable relief, in the circuit court of the county in which the site is located or in Marion County, as may be necessary:

(a) To enforce an order issued under subsection (3) of this section; or

(b) To abate any imminent and substantial danger to the public health, safety, welfare or the environment related to a release.

(5) Notwithstanding any provision of ORS chapter 183, any order issued by the director under subsection (3) of this section shall not be appealable to the Environmental Quality Commission or subject to judicial review.

(6) If any person who is liable under ORS 475.455 fails without sufficient cause to conduct a cleanup action as required by an order of the director, the person shall be liable to the Department of Environmental Quality for the state's cleanup costs and for punitive damages not to exceed three times the amount of the state's cleanup costs.

(7) Nothing in this section is intended to interfere with, limit or abridge the authority of the State Fire Marshal or any other state agency or local unit of government relating to an emergency that presents a combustion or explosion hazard. [1987 c.699 §6]

475.445 Site entry; purposes. (1) Upon request of a law enforcement agency under ORS 475.415, the Department of Environmental Quality or its authorized representative may enter any alleged illegal drug manufacturing site at any reasonable time to:

(a) Sample, inspect, examine and investigate;

(b) Examine and copy records and other information; or

(c) Carry out cleanup action authorized by ORS 475.415 to 475.455, 475.475 and 475.485.

(2) If any person refuses to provide information, documents, records or to allow entry under subsection (1) of this section, the department may request the Attorney General to seek from a court of competent jurisdiction an order requiring the person to provide such information, documents, records or to allow entry. [1987 c.699 §4]

475.455 Liability of certain persons for cleanup costs. (1) The following persons shall be strictly liable for those cleanup costs incurred by the state or any other person that are attributable to or associated with an alleged illegal drug manufacturing site and for damages for injury to or destruction of any natural resources caused by chemicals at the site:

(a) Any owner or operator at or during the time of the acts or omissions that resulted in a site being created or damage to natural resources.

(b) Any owner or operator who became the owner or operator after the time of the acts or omissions that resulted in a site being created or damages, and who knew or reasonably should have known of the site or damages when the person first became the owner or operator.

(c) Any owner or operator who obtained actual knowledge of the site or damages during the time the person was the owner or operator of the site and then subsequently transferred ownership or operation of the site to another person without disclosing such knowledge.

(d) Any person who, by any acts or omissions, caused, contributed to or exacerbated the site or damage, unless the acts or omissions were in material compliance with applicable laws, standards, regulations, licenses or permits.

(e) Any person who unlawfully hinders or delays entry to, investigation of or cleanup action at a site.

(2) Except as provided in subsection (1)(b) to (e) of this section and subsection (4) of this section, the following persons shall not be liable for cleanup costs incurred by the state or any other person that are attributable to or associated with a site, or for damages for injury to or destruction of any natural resources caused by chemicals at the site:

(a) Any owner or operator who became the owner or operator after the time of the acts or omissions that resulted in the site being created or damages, and who did not know and reasonably should not have known of the damages when the person first became the owner or operator.

(b) Any owner or operator of property that was contaminated by the migration of chemicals from real property not owned or operated by the person.

(c) Any owner or operator at or during the time of the acts or omissions that resulted in the site or damages, if the site or damage at the site was caused solely by one or a combination of the following:

(A) An act of God. “Act of God” means an unanticipated grave natural disaster or other natural phenomenon of an exceptional, inevitable and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight.

(B) An act of war.

(C) Acts or omissions of a third party, other than an employee or agent of the person asserting this defense, or other than a person whose acts or omissions occur in connection with a contractual relationship, existing directly or indirectly, with the person asserting this defense. As used in this subparagraph, “contractual relationship” includes but is not limited to land contracts, deeds or other instruments transferring title or possession.

(3) Except as provided in subsection (1)(c) to (e) of this section or subsection (4) of this section, the following persons shall not be liable for cleanup costs incurred by the state or any other person that are attributable to or associated with an alleged illegal drug manufacturing site, or for damages for injury to or destruction of any natural resources caused by chemicals at the site:

(a) A unit of state or local government that acquired ownership or control of a site in the following ways:

(A) Involuntarily by virtue of its function as sovereign, including but not limited to escheat, bankruptcy, tax delinquency or abandonment; or

(B) Through the exercise of eminent domain authority by purchase or condemnation.

(b) A person who acquired a site by inheritance or bequest.

(4) Notwithstanding the exclusions from liability provided for specified persons in subsections (2) and (3) of this section, such persons shall be liable for cleanup costs incurred by the state or any other person that are attributable to or associated with a site, and for damages for injury to or destruction of any natural resources caused by chemicals at a site, to the extent that the person’s acts or omissions contribute to such costs or damages, if the person:

(a) Obtained actual knowledge of the chemicals at a site or damages and then failed to promptly notify the Department of Environmental Quality and exercise due care with respect to the chemicals concerned, taking into consideration the characteristics of the chemicals in light of all relevant facts and circumstances; or

(b) Failed to take reasonable precautions against the reasonably foreseeable acts or omissions of a third party and the reasonably foreseeable consequences of such acts or omissions.

(5)(a) No indemnification, hold harmless, or similar agreement or conveyance shall be effective to transfer from any person who may be liable under this section, to any other person, the liability imposed under this section. Nothing in this section shall bar any agreement to insure, hold harmless or indemnify a party to such agreement for any liability under this section.

(b) A person who is liable under this section shall not be barred from seeking contribution from any other person for liability under this section.

(c) Nothing in ORS 475.415 to 475.455, 475.475 and 475.485 shall bar a cause of action that a person liable under this section or a guarantor has or would have by reason of subrogation or otherwise against any person.

(d) Nothing in this section shall restrict any right that the state or any person might have under federal statute, common law or other state statute to recover cleanup costs or to seek any other relief related to the cleanup of an alleged illegal drug manufacturing site.

(6) To establish, for purposes of subsection (1)(b) of this section or subsection (2)(a) of this section, that the person did or did not have reason to know, the person must have undertaken, at the time of acquisition, all appropriate inquiry into the previous ownership and uses of the

property consistent with good commercial or customary practice in an effort to minimize liability.

(7)(a) Except as provided in paragraph (b) of this subsection, no person shall be liable under ORS 475.415 to 475.455, 475.475 and 475.485 for costs or damages as a result of actions taken or omitted in the course of rendering care, assistance or advice in accordance with rules adopted by the Environmental Quality Commission or at the direction of the department or its authorized representative, with respect to an incident creating a danger to public health, safety, welfare or the environment as a result of any cleanup of a site. This paragraph shall not preclude liability for costs or damages as the result of negligence on the part of such person.

(b) No state or local government shall be liable under this section for costs or damages as a result of actions taken in response to an emergency created by the chemicals at or generated by or from a site owned by another person. This paragraph shall not preclude liability for costs or damages as a result of gross negligence or intentional misconduct by the state or local government. For the purpose of this paragraph, reckless, willful or wanton misconduct shall constitute gross negligence.

(c) This subsection shall not alter the liability of any person covered by subsection (1) of this section. [1987 c.699 §5]

475.465 Liability of state for cleanup. Notwithstanding any other provision of law, the State of Oregon, the Environmental Quality Commission and the Department of Environmental Quality and their officers, employees and agents shall not be liable to a person possessing or owning chemicals located at an alleged illegal drug manufacturing site for any claims or actions arising from the identification, cleanup, storage or disposal of such chemicals by the Department of Environmental Quality. [1987 c.699 §10]

475.475 Department record of costs; collection of costs. (1) The Department of Environmental Quality shall keep a record of the state's cleanup costs.

(2) Based on the record compiled by the department under subsection (1) of this section, the department shall require any person liable under ORS 475.435 or 475.455 to pay the amount of the state's cleanup costs and, if applicable, punitive damages.

(3) If the state's cleanup costs and punitive damages are not paid by the liable person to the department within 45 days after receipt of notice that such costs and damages are due and owing, the Attorney General, at the request of the Director of the Department of Environmental Quality, shall bring an action in the name of the State of Oregon in a court of competent jurisdiction to recover the amount owed, plus reasonable legal expenses.

(4) All moneys received by the department under this section shall be deposited in the Illegal Drug Cleanup Fund established under ORS 475.495. [1987 c.699 §7]

475.485 Costs and penalties as lien; enforcement of lien. (1) All of the state's cleanup costs, penalties and punitive damages for which a person is liable to the state under ORS 475.435 or 475.455 shall constitute a lien upon any real and personal property owned by the person.

(2) At the discretion of the Department of Environmental Quality, the department may file a claim of lien on real property or a claim of lien on personal property. The department shall file a claim of lien on real property to be charged with a lien under this section with the recording officer of each county in which the real property is located and shall file a claim of lien on personal property to be charged with a lien under this section with the Secretary of State. The lien shall attach and become enforceable on the day of such filing. The lien claim shall contain:

(a) A statement of the demand;

(b) The name of the person against whose property the lien attaches;

(c) A description of the property charged with the lien sufficient for identification; and

(d) A statement of the failure of the person to conduct cleanup action and pay penalties and damages as required.

(3) The lien created by this section may be foreclosed by a suit on real and personal property in the circuit court in the manner provided by law for the foreclosure of other liens.

(4) Nothing in this section shall affect the right of the state to bring an action against any person to recover all costs and damages for which the person is liable under ORS 475.435 or 475.455.

(5) A lien created under this section shall have priority over any claim of the state under ORS 166.715 to 166.735 or any local government forfeiture ordinance or regulation. [1987 c.699 §8]

475.495 Illegal Drug Cleanup Fund; sources; uses. (1) The Illegal Drug Cleanup Fund is established separate and distinct from the General Fund in the State Treasury.

(2) The following moneys shall be deposited into the State Treasury and credited to the Illegal Drug Cleanup Fund:

(a) Moneys recovered or otherwise received from responsible parties for cleanup costs;

(b) Moneys received from a state agency, local government unit or any agency of a local government unit for cleanup of illegal drug manufacturing sites, including moneys received from forfeiture proceeds under the provisions of ORS 131A.360 and 131A.365;

(c) Moneys received from the federal government for cleanup of illegal drug manufacturing sites; and

(d) Any penalty or punitive damages recovered under ORS 475.435, 475.455 or 475.485.

(3) The State Treasurer may invest and reinvest moneys in the Illegal Drug Cleanup Fund in the manner provided by law. Interest earned by the fund shall be credited to the fund.

(4) The moneys in the Illegal Drug Cleanup Fund are appropriated continuously to the Department of Environmental Quality to be used as provided for in subsection (5) of this section.

(5) Moneys in the Illegal Drug Cleanup Fund may be used for the following purposes:

(a) Payment of the state's cleanup costs;

(b) Funding any action or activity authorized by ORS 475.415 to 475.455, 475.475 and 475.485; and

(c) Funding safety certification training and personal protective equipment for law enforcement personnel assigned to respond to illegal drug manufacturing sites.

(6) In addition to the purposes provided for in subsection (5) of this section, moneys in the Illegal Drug Cleanup Fund received from forfeiture proceeds under the provisions of ORS 131A.360 and 131A.365 may be transferred to the Oregon Health Authority to support the administration of the illegal drug manufacturing cleanup program provided for in ORS 453.855 to 453.912.

(7) The department may not expend more than $250,000 in each biennium of the forfeiture proceeds that are paid into the Illegal Drug Cleanup Fund by political subdivisions under the provisions of ORS 131A.360. If at the end of a biennium more than $250,000 has been paid into the Illegal Drug Cleanup Fund under the provisions of ORS 131A.360, the department shall refund to each political subdivision that made payments into the fund a pro rata share of the excess amount, based on the amount of forfeiture proceeds paid into the fund by the political subdivision. [1987 c.699 §9; 1989 c.966 §56; 1993 c.699 §5; 2001 c.780 §§19,19a; 2009 c.78 §52; 2011 c.524 §1; 2011 c.597 §217; 2011 c.720 §205a]

475.505 [1979 c.253 §1; repealed by 1987 c.75 §1]

475.510 [1979 c.253 §2; repealed by 1987 c.75 §1]

475.515 [1979 c.253 §3; repealed by 1987 c.75 §1]

DRUG PARAPHERNALIA

475.525 Sale of drug paraphernalia prohibited; definition of drug paraphernalia; exceptions. (1) It is unlawful for any person to sell or deliver, possess with intent to sell or deliver or manufacture with intent to sell or deliver drug paraphernalia, knowing that it will be used to unlawfully plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale or otherwise introduce into the human body a controlled substance as defined by ORS 475.005.

(2) For the purposes of this section, "drug paraphernalia" means all equipment, products and materials of any kind which are marketed for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance in violation of ORS 475.840 to 475.980. Drug paraphernalia includes, but is not limited to:

(a) Kits marketed for use or designed for use in unlawfully planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived;

(b) Kits marketed for use or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances;

(c) Isomerization devices marketed for use or designed for use in increasing the potency of any species of plant which is a controlled substance;

(d) Testing equipment marketed for use or designed for use in identifying or in analyzing the strength, effectiveness or purity of controlled substances;

(e) Scales and balances marketed for use or designed for use in weighing or measuring controlled substances;

(f) Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, marketed for use or designed for use in cutting controlled substances;

(g) Separation gins and sifters marketed for use or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining marijuana;

(h) Containers and other objects marketed for use or designed for use in storing or concealing controlled substances; and

(i) Objects marketed for use or designed specifically for use in ingesting, inhaling or otherwise introducing marijuana, cocaine, hashish or hashish oil into the human body, such as:

(A) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens or hashish heads;

(B) Water pipes;

(C) Carburetion tubes and devices;

(D) Smoking and carburetion masks;

(E) Roach clips, meaning objects used to hold burning material that has become too small or too short to be held in the hand, such as a marijuana cigarette;

(F) Miniature cocaine spoons and cocaine vials;

(G) Chamber pipes;

(H) Carburetor pipes;

(I) Electric pipes;

(J) Air-driven pipes;

(K) Chillums;
(L) Bongs;
(M) Ice pipes or chillers; and
(N) Lighting equipment specifically designed for the growing of controlled substances.
(3) "Drug paraphernalia" does not include hypodermic syringes or needles.
(4) For the purposes of this section, "marijuana paraphernalia" means all equipment, products and materials of any kind which are marketed for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body marijuana in violation of ORS 475.840 to 475.980.
(5) In determining whether an object is drug paraphernalia or marijuana paraphernalia, a trier of fact should consider, in addition to all other relevant factors, the following:
(a) Instructions, oral or written, provided with the object concerning its use;
(b) Descriptive materials accompanying the object which explain or depict its use;
(c) National and local advertising concerning its use;
(d) The manner in which the object is displayed for sale;
(e) The existence and scope of legitimate uses for the object in the community; and
(f) Any expert testimony which may be introduced concerning its use.
(6) The provisions of ORS 475.525 to 475.565 do not apply to persons registered under the provisions of ORS 475.125 or to persons specified as exempt from registration under the provisions of that statute.
(7) The provisions of ORS 475.525 to 475.565 do not apply to a person who sells or delivers marijuana paraphernalia to a person 21 years of age or older. [1989 c.1077 §1; 1995 c.440 §10; 2015 c.1 §75]

Note: 475.840 was renumbered 475.752 in 2011. The text of 475.525 set forth in section 75, chapter 1, Oregon Laws 2015, did not reflect the renumbering. Editorial adjustment of 475.525 for the renumbering of 475.840 has not been made.

475.535 Action to enforce ORS 475.525 to 475.565. The State of Oregon, any political subdivision of the state, or any official or agency of the state or its political subdivisions may bring an action to enforce ORS 475.525 to 475.565. The court shall award costs and reasonable attorney fees to the prevailing party in any such action. [1989 c.1077 §2]

475.545 Order of forfeiture of paraphernalia; effect. If, at the trial or upon a hearing, the trier of fact finds any item received into evidence at the trial or hearing to be drug paraphernalia, the court may order the item forfeited upon motion of the district attorney. The drug paraphernalia may then be destroyed or, if the paraphernalia is of substantial value and is not contraband, may be sold, the proceeds to be deposited in the Common School Fund. [1989 c.1077 §3]

475.555 Seizure of drug paraphernalia. An official of the state, its political subdivisions or any agency thereof may seize drug paraphernalia when:
(1) The drug paraphernalia is the subject of an adverse judgment under ORS 475.525 to 475.565;
(2) The seizure is in the course of a constitutionally valid arrest or search;
(3) The owner or person in possession of the drug paraphernalia consents to the seizure; or
(4) The seizure is pursuant to a lawful order of a court, including an order issued under ORCP 83 or ORS 166.725. [1989 c.1077 §5]

475.565 Civil penalty for violation of ORS 475.525. (1) In addition to any other penalty provided by law:

(a) A person who violates ORS 475.525 shall incur a civil penalty in an amount of at least $2,000 and not more than $10,000; and

(b) The court may order other equitable remedies including but not limited to injunctive relief.

(2) Any amounts collected under this section shall be forwarded to the State Treasurer for deposit in the General Fund to the credit of the Oregon Health Authority. The moneys shall be used for the development and implementation of drug abuse prevention activities and adolescent treatment. [1989 c.1077 §4; 2003 c.14 §307; 2009 c.595 §975; 2011 c.597 §218]

475.610 [1955 c.573 §2; 1957 c.587 §9; repealed by 1959 c.411 §2 (475.615 enacted in lieu of 475.610)]

475.615 [1959 c.411 §3 (enacted in lieu of 475.610); repealed by 1977 c.745 §54]

475.620 [1955 c.573 §3; 1957 c.587 §10; repealed by 1959 c.411 §4 (475.625 enacted in lieu of 475.620)]

475.625 [1959 c.411 §5 (enacted in lieu of 475.620); 1963 c.137 §2; 1969 c.310 §2; repealed by 1971 c.743 §432]

475.630 [1955 c.573 §4; repealed by 1959 c.411 §6 (475.655 enacted in lieu of 475.630)]

475.635 [1959 c.411 §11 (enacted in lieu of 475.650); 1969 c.310 §3; repealed by 1971 c.743 §432]

475.640 [1955 c.573 §5; repealed by 1959 c.411 §8 (475.665 enacted in lieu of 475.640)]

475.645 [1959 c.411 §21 (enacted in lieu of 475.700); 1969 c.391 §15; 1971 c.743 §380; 1973 c.697 §20; 1977 c.745 §41; repealed by 1977 c.871 §29]

475.650 [1955 c.573 §6; repealed by 1959 c.411 §10 (475.635 enacted in lieu of 475.650)]

475.655 [1959 c.411 §7 (enacted in lieu of 475.630); 1963 c.137 §3; 1971 c.743 §381; repealed by 1973 c.697 §21]

475.660 [1955 c.573 §7; repealed by 1959 c.411 §12 (475.675 enacted in lieu of 475.660)]

475.665 [1959 c.411 §9 (enacted in lieu of 475.640); 1971 c.743 §382; 1973 c.697 §17; 1977 c.745 §42; repealed by 1977 c.871 §29]

475.670 [1955 c.573 §8; repealed by 1959 c.411 §14 (475.705 enacted in lieu of 475.670)]

475.675 [1959 c.411 §13 (enacted in lieu of 475.660); 1969 c.638 §2; 1973 c.697 §18; repealed by 1977 c.871 §29]

475.680 [1955 c.573 §§9,13; repealed by 1959 c.411 §16 (475.685 enacted in lieu of 475.680)]

475.685 [1959 c.411 §17 (enacted in lieu of 475.680); 1973 c.697 §15; repealed by 1977 c.871 §29]

475.690 [1955 c.573 §9; repealed by 1959 c.411 §18 (475.695 enacted in lieu of 475.690)]

475.695 [1959 c.411 §19 (enacted in lieu of 475.690); 1973 c.697 §16; 1977 c.745 §48; repealed by 1977 c.871 §29]

475.700 [1955 c.573 §10; repealed by 1959 c.411 §20 (475.645 enacted in lieu of 475.700)]

475.705 [1959 c.411 §15 (enacted in lieu of 475.670); 1969 c.638 §3; 1973 c.697 §19; 1977 c.745 §49; repealed by 1977 c.871 §29]

475.710 [1955 c.573 §11; repealed by 1959 c.411 §22]

475.715 [1969 c.442 §1; renumbered 430.560]

475.720 [1955 c.573 §12; repealed by 1959 c.411 §22]

475.725 [1969 c.442 §2; renumbered 430.565]

475.730 [1955 c.573 §13; repealed by 1959 c.411 §22]

475.732 [1973 c.697 §12; repealed by 1977 c.745 §54 and 1977 c.871 §29]

475.740 [1955 c.573 §1; repealed by 1959 c.411 §22]

475.742 [1973 c.697 §14; repealed by 1977 c.871 §29]

475.744 Providing hypodermic device to minor prohibited; exception. (1) No person shall sell or give a hypodermic device to a minor unless the minor demonstrates a lawful need therefor by authorization of a physician, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, parent or legal guardian or by other means acceptable to the seller or donor.

(2) As used in this section, "hypodermic device" means a hypodermic needle or syringe or medication packaged in a hypodermic syringe or any instrument adapted for the subcutaneous injection of a controlled substance as defined in ORS 475.005. [Formerly 475.805; 2014 c.45 §65]

475.750 [1955 c.573 §3; repealed by 1959 c.411 §22]

PENALTIES

475.752 Prohibited acts generally; penalties; exceptions; affirmative defense for certain peyote uses; causing death by Schedule IV substance. (1) Except for licensees and licensee representatives, as those terms are defined in ORS 475B.015, that are engaged in lawful activities, and except for a person acting within the scope of and in compliance with ORS 475B.245, and except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is

unlawful for any person to manufacture or deliver a controlled substance. Any person who violates this subsection with respect to:

(a) A controlled substance in Schedule I, is guilty of a Class A felony, except as otherwise provided in ORS 475.886 and 475.890.

(b) A controlled substance in Schedule II, is guilty of a Class B felony, except as otherwise provided in ORS 475.858, 475.860, 475.862, 475.878, 475.880, 475.882, 475.904 and 475.906.

(c) A controlled substance in Schedule III, is guilty of a Class C felony, except as otherwise provided in ORS 475.904 and 475.906.

(d) A controlled substance in Schedule IV, is guilty of a Class B misdemeanor.

(e) A controlled substance in Schedule V, is guilty of a Class C misdemeanor.

(2) Except as authorized in ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to create or deliver a counterfeit substance. Any person who violates this subsection with respect to:

(a) A counterfeit substance in Schedule I, is guilty of a Class A felony.

(b) A counterfeit substance in Schedule II, is guilty of a Class B felony.

(c) A counterfeit substance in Schedule III, is guilty of a Class C felony.

(d) A counterfeit substance in Schedule IV, is guilty of a Class B misdemeanor.

(e) A counterfeit substance in Schedule V, is guilty of a Class C misdemeanor.

(3) It is unlawful for any person knowingly or intentionally to possess a controlled substance, other than marijuana, unless the substance was obtained directly from, or pursuant to a valid prescription or order of, a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980. Any person who violates this subsection with respect to:

(a) A controlled substance in Schedule I, is guilty of a Class B felony, except as otherwise provided in ORS 475.894.

(b) A controlled substance in Schedule II, is guilty of a Class C felony, except as otherwise provided in ORS 475.864.

(c) A controlled substance in Schedule III, is guilty of a Class A misdemeanor.

(d) A controlled substance in Schedule IV, is guilty of a Class C misdemeanor.

(e) A controlled substance in Schedule V, is guilty of a violation.

(4) In any prosecution under this section for manufacture, possession or delivery of that plant of the genus Lophophora commonly known as peyote, it is an affirmative defense that the peyote is being used or is intended for use:

(a) In connection with the good faith practice of a religious belief;

(b) As directly associated with a religious practice; and

(c) In a manner that is not dangerous to the health of the user or others who are in the proximity of the user.

(5) The affirmative defense created in subsection (4) of this section is not available to any person who has possessed or delivered the peyote while incarcerated in a correctional facility in this state.

(6)(a) Notwithstanding subsection (1) of this section, a person who unlawfully manufactures or delivers a controlled substance in Schedule IV and who thereby causes death to another person is guilty of a Class C felony.

(b) For purposes of this subsection, causation is established when the controlled substance plays a substantial role in the death of the other person. [Formerly 475.840; 2013 c.591 §3; 2015 c.1 §76; 2015 c.614 §124]

475.754 Affirmative defense to unlawfully possessing pseudoephedrine. It is an affirmative defense to a charge of violating ORS 475.752 by unlawfully possessing pseudoephedrine that the person:

(1) Obtained the pseudoephedrine lawfully;

(2) Possessed no more than six grams of pseudoephedrine, the salts, isomers or salts of isomers of pseudoephedrine or a combination of any of these substances; and

(3) Possessed the pseudoephedrine under circumstances that are consistent with typical medicinal or household use, as indicated by factors that include but are not limited to storage location, purchase date, possession of the products in a variety of strengths, brands, types or purposes and expiration date. [Formerly 475.843]

Note: 475.754 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.805 [1983 c.738 §1; renumbered 475.744 in 2011]

475.806 Unlawful manufacture of hydrocodone. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture hydrocodone.

(2) Unlawful manufacture of hydrocodone is a Class C felony. [2011 c.524 §11]

475.808 Unlawful manufacture of hydrocodone within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture hydrocodone within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of hydrocodone within 1,000 feet of a school is a Class B felony. [2011 c.524 §12]

475.810 Unlawful delivery of hydrocodone. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver hydrocodone.

(2) Unlawful delivery of hydrocodone is a Class C felony.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of hydrocodone is a Class B felony if the delivery is to a person under 18 years of age. [2011 c.524 §13]

475.812 Unlawful delivery of hydrocodone within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver hydrocodone within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of hydrocodone within 1,000 feet of a school is a Class B felony. [2011 c.524 §14]

475.814 Unlawful possession of hydrocodone. (1) It is unlawful for any person knowingly or intentionally to possess hydrocodone unless the hydrocodone was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2) Unlawful possession of hydrocodone is a Class A misdemeanor. [2011 c.524 §15]

475.816 Unlawful manufacture of methadone. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture methadone.

(2) Unlawful manufacture of methadone is a Class B felony. [2011 c.524 §16]

475.818 Unlawful manufacture of methadone within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture methadone within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of methadone within 1,000 feet of a school is a Class A felony. [2011 c.524 §17]

475.820 Unlawful delivery of methadone. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver methadone.

(2) Unlawful delivery of methadone is a Class B felony.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of methadone is a Class A felony if the delivery is to a person under 18 years of age. [2011 c.524 §18]

475.822 Unlawful delivery of methadone within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver methadone within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of methadone within 1,000 feet of a school is a Class A felony. [2011 c.524 §19]

475.824 Unlawful possession of methadone. (1) It is unlawful for any person knowingly or intentionally to possess methadone unless the methadone was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2) Unlawful possession of methadone is a Class C felony. [2011 c.524 §20]

475.826 Unlawful manufacture of oxycodone. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture oxycodone.

(2) Unlawful manufacture of oxycodone is a Class B felony. [2011 c.524 §6]

475.828 Unlawful manufacture of oxycodone within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture oxycodone within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of oxycodone within 1,000 feet of a school is a Class A felony. [2011 c.524 §7]

475.830 Unlawful delivery of oxycodone. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver oxycodone.

(2) Unlawful delivery of oxycodone is a Class B felony.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of oxycodone is a Class A felony if the delivery is to a person under 18 years of age. [2011 c.524 §8]

475.832 Unlawful delivery of oxycodone within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver

oxycodone within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of oxycodone within 1,000 feet of a school is a Class A felony. [2011 c.524 §9]

475.834 Unlawful possession of oxycodone. (1) It is unlawful for any person knowingly or intentionally to possess oxycodone unless the oxycodone was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2) Unlawful possession of oxycodone is a Class C felony. [2011 c.524 §10]

475.840 [Formerly 475.992; 2009 c.898 §1; renumbered 475.752 in 2011]

475.843 [2005 c.706 §13a; renumbered 475.754 in 2011]

475.846 Unlawful manufacture of heroin. (1) It is unlawful for any person to manufacture heroin.

(2) Unlawful manufacture of heroin is a Class A felony. [2005 c.708 §24]

475.848 Unlawful manufacture of heroin within 1,000 feet of school. (1) It is unlawful for any person to manufacture heroin within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of heroin within 1,000 feet of a school is a Class A felony. [2005 c.708 §25]

475.850 Unlawful delivery of heroin. (1) It is unlawful for any person to deliver heroin.

(2) Unlawful delivery of heroin is a Class A felony. [2005 c.708 §26]

475.852 Unlawful delivery of heroin within 1,000 feet of school. (1) It is unlawful for any person to deliver heroin within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of heroin within 1,000 feet of a school is a Class A felony. [2005 c.708 §27]

475.854 Unlawful possession of heroin. (1) It is unlawful for any person knowingly or intentionally to possess heroin.

(2) Unlawful possession of heroin is a Class B felony. [2005 c.708 §28]

475.856 Unlawful manufacture of marijuana; exceptions. (1) As used in this section, "homegrown," "household," "license" and "licensee representative" have the meanings given those terms in ORS 475B.015.

(2) Except for licensees and licensee representatives that are engaged in lawful activities, and except for a person acting within the scope of and in compliance with ORS 475B.245, it is unlawful for any person to manufacture marijuana.

(3) Unlawful manufacture of marijuana is a Class C felony.

(4) Notwithstanding subsection (3) of this section, unlawful manufacture of marijuana is a Class B misdemeanor if a person 21 years of age or older manufactures homegrown marijuana at a household and the total number of homegrown marijuana plants at the household exceeds four

marijuana plants but does not exceed eight marijuana plants. [2005 c.708 §29; 2013 c.591 §1; 2015 c.1 §77; 2015 c.614 §121]

475.858 Unlawful manufacture of marijuana within 1,000 feet of school; exceptions. (1) It is unlawful for any person to manufacture marijuana within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of marijuana within 1,000 feet of a school is a Class A felony.

(3) This section does not apply to:

(a) A licensee or licensee representative, as those terms are defined in ORS 475B.015, that is engaged in lawful activities; or

(b) A person acting within the scope of and in compliance with ORS 475B.245. [2005 c.708 §30; 2015 c.614 §119]

475.860 Unlawful delivery of marijuana; exceptions. (1) Except for licensees and licensee representatives, as those terms are defined in ORS 475B.015, that are engaged in lawful activities, and except for a person acting within the scope of and in compliance with ORS 475B.245, it is unlawful for any person to deliver marijuana.

(2) Unlawful delivery of marijuana is a Class A misdemeanor.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of marijuana is a:

(a) Class A violation, if the delivery is for no consideration and consists of less than one avoirdupois ounce of the dried leaves, stems and flowers of the plant Cannabis family Moraceae; or

(b) Violation, if the delivery is for no consideration and consists of less than five grams of the dried leaves, stems and flowers of the plant Cannabis family Moraceae. A violation under this paragraph is a specific fine violation. The presumptive fine for a violation under this paragraph is $650.

(4) Notwithstanding subsections (2) and (3) of this section, unlawful delivery of marijuana is a Class C felony, if the delivery is to a person under 18 years of age and the defendant is at least 21 years of age. [2005 c.708 §31; 2009 c.610 §1; 2011 c.597 §88; 2015 c.1 §78; 2015 c.614 §122]

475.862 Unlawful delivery of marijuana within 1,000 feet of school; exceptions. (1) It is unlawful for any person to deliver marijuana within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of marijuana within 1,000 feet of a school is a Class A felony.

(3) This section does not apply to:

(a) A licensee or licensee representative, as those terms are defined in ORS 475B.015, that is engaged in lawful activities; or

(b) A person acting within the scope of and in compliance with ORS 475B.245. [2005 c.708 §32; 2015 c.614 §120]

475.864 Unlawful possession of marijuana or marijuana product; exceptions. (1) As used in subsections (2) to (4) of this section:

(a) "Marijuana" means the leaves, stems and flowers of the plant Cannabis family Moraceae.

(b) "Marijuana product" has the meaning given the term "marijuana" in ORS 475.005 (16), but does not include the leaves, stems and flowers of the plant Cannabis family Moraceae.

(2) It is unlawful for any person under 21 years of age knowingly or intentionally to possess marijuana or marijuana product.

(3)(a) Unlawful possession of more than eight avoirdupois ounces of marijuana by a person under 21 years of age is a Class A misdemeanor.

(b) Unlawful possession of more than one avoirdupois ounce of marijuana, but less than eight avoirdupois ounces, by a person under 21 years of age is a Class B misdemeanor.

(c) Unlawful possession of one avoirdupois ounce or less of marijuana by a person under 21 years of age is a specific fine violation. The presumptive fine for a violation under this paragraph is $650.

(4)(a) Unlawful possession of more than 16 avoirdupois ounces of marijuana product in a solid form or more than 72 ounces of marijuana product in a liquid form by a person under 21 years of age is a Class A misdemeanor.

(b) Unlawful possession of 16 avoirdupois ounces or less of marijuana product in a solid form or 72 ounces or less of marijuana product in a liquid form by a person under 21 years of age is a Class B misdemeanor.

(5) As used in subsections (6) to (8) of this section, “cannabinoid concentrate,” “cannabinoid extract,” “cannabinoid product,” “licensee,” “licensee representative,” “marijuana,” “marijuana retailer,” “public place” and “usable marijuana” have the meanings given those terms in ORS 475B.015.

(6) Except for licensees and licensee representatives acting in accordance with ORS 475B.010 to 475B.395, and any rule adopted under ORS 475B.010 to 475B.395, it is unlawful for any person 21 years of age or older knowingly or intentionally to possess:

(a) More than one ounce of usable marijuana in a public place.

(b) More than eight ounces of usable marijuana.

(c) More than 16 ounces of cannabinoid products in solid form or cannabinoid concentrates.

(d) More than 72 ounces of cannabinoid products in liquid form.

(e) More than one ounce of cannabinoid extracts.

(f) A cannabinoid extract that was not purchased from a marijuana retailer that holds a license under ORS 475B.110.

(7) A violation of subsection (6)(a) to (e) of this section is a:

(a) Class A misdemeanor, if the amount possessed is more than four times the applicable maximum amount specified in subsection (6)(a) to (e) of this section;

(b) Class B misdemeanor, if the amount possessed is more than two times, but not more than four times, the applicable maximum amount specified in subsection (6)(a) to (e) of this section; or

(c) Class B violation, if the amount possessed is not more than two times the applicable maximum amount specified in subsection (6)(a) to (e) of this section.

(8) A violation of subsection (6)(f) of this section is a:

(a) Class C felony, if the amount possessed is more than one-quarter ounce of the cannabinoid extract; or

(b) Class B misdemeanor, if the amount possessed is not more than one-quarter ounce of the cannabinoid extract. [2005 c.708 §33; 2011 c.597 §89; 2013 c.591 §2; 2015 c.1 §79; 2015 c.614 §123]

475.866 Unlawful manufacture of 3,4-methylenedioxymethamphetamine. (1) It is unlawful for any person to manufacture 3,4-methylenedioxymethamphetamine.

(2) Unlawful manufacture of 3,4-meth- ylenedioxymethamphetamine is a Class A felony. [2005 c.708 §34]

475.868 Unlawful manufacture of 3,4-methylenedioxymethamphetamine within 1,000 feet of school. (1) It is unlawful for any person to manufacture 3,4-methylenedioxymethamphetamine

within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of 3,4-methylenedioxymethamphetamine within 1,000 feet of a school is a Class A felony. [2005 c.708 §35]

475.870 Unlawful delivery of 3,4-methylenedioxymethamphetamine. (1) It is unlawful for any person to deliver 3,4-methylenedioxymethamphetamine.

(2) Unlawful delivery of 3,4-methylenedi- oxymethamphetamine is a Class A felony. [2005 c.708 §36]

475.872 Unlawful delivery of 3,4-methylenedioxymethamphetamine within 1,000 feet of school. (1) It is unlawful for any person to deliver 3,4-methylenedioxymethamphetamine within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of 3,4-methylenedi- oxymethamphetamine within 1,000 feet of a school is a Class A felony. [2005 c.708 §37]

475.874 Unlawful possession of 3,4-methylenedioxymethamphetamine. (1) It is unlawful for any person knowingly or intentionally to possess 3,4-methylenedioxy-methamphetamine.

(2) Unlawful possession of 3,4-methylene-dioxymethamphetamine is a Class B felony. [2005 c.708 §38]

475.876 Unlawful manufacture of cocaine. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture cocaine.

(2) Unlawful manufacture of cocaine is a Class B felony. [2005 c.708 §19]

475.878 Unlawful manufacture of cocaine within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture cocaine within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of cocaine within 1,000 feet of a school is a Class A felony. [2005 c.708 §20]

475.880 Unlawful delivery of cocaine. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver cocaine.

(2) Unlawful delivery of cocaine is a Class B felony.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of cocaine is a Class A felony if the delivery is to a person under 18 years of age. [2005 c.708 §21]

475.882 Unlawful delivery of cocaine within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver cocaine within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of cocaine within 1,000 feet of a school is a Class A felony. [2005 c.708 §22]

475.884 Unlawful possession of cocaine. (1) It is unlawful for any person knowingly or intentionally to possess cocaine unless the substance was obtained directly from, or pursuant to, a

valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2) Unlawful possession of cocaine is a Class C felony. [2005 c.708 §23]

475.886 Unlawful manufacture of methamphetamine. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture methamphetamine.

(2) Unlawful manufacture of methamphetamine is a Class B felony.

(3) The minimum fine for unlawful manufacture of methamphetamine is $1,000. [2005 c.708 §14; 2011 c.597 §11]

475.888 Unlawful manufacture of methamphetamine within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture methamphetamine within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture of methamphetamine within 1,000 feet of a school is a Class A felony.

(3) The minimum fine for unlawful manufacture of methamphetamine within 1,000 feet of a school is $1,000. [2005 c.708 §15; 2011 c.597 §12]

475.890 Unlawful delivery of methamphetamine. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver methamphetamine.

(2) Unlawful delivery of methamphetamine is a Class B felony.

(3) Notwithstanding subsection (2) of this section, unlawful delivery of methamphetamine is a Class A felony if the delivery is to a person under 18 years of age.

(4) The minimum fine for unlawful delivery of methamphetamine is $500. [2005 c.708 §16; 2011 c.597 §13]

475.892 Unlawful delivery of methamphetamine within 1,000 feet of school. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver methamphetamine within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful delivery of methamphetamine within 1,000 feet of a school is a Class A felony.

(3) The minimum fine for unlawful delivery of methamphetamine within 1,000 feet of a school is $500. [2005 c.708 §17; 2011 c.597 §14]

475.894 Unlawful possession of methamphetamine. (1) It is unlawful for any person knowingly or intentionally to possess methamphetamine unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of professional practice, or except as otherwise authorized by ORS 475.005 to 475.285 and 475.752 to 475.980.

(2) Unlawful possession of methamphetamine is a Class C felony. [2005 c.708 §18]

475.898 Immunity from drug-related offenses for emergency medical assistance. (1) A person who contacts emergency medical services or a law enforcement agency to obtain medical assistance for another person who needs medical assistance due to a drug-related overdose is immune from arrest or prosecution for an offense listed in subsection (3) of this section if the evidence of the offense was obtained because the person contacted emergency medical services or a law enforcement agency.

(2) A person who is in need of medical assistance due to a drug-related overdose is immune from arrest or prosecution for an offense listed in subsection (3) of this section if the evidence of the offense was obtained because any person contacted emergency medical services or a law enforcement agency to obtain medical assistance for the person.

(3) The immunity conferred under subsections (1) and (2) of this section applies to arrest and prosecution for:

(a) Frequenting a place where controlled substances are used as described in ORS 167.222;

(b) Possession of a controlled substance as described in ORS 475.752;

(c) Unlawful possession of hydrocodone as described in ORS 475.814;

(d) Unlawful possession of methadone as described in ORS 475.824;

(e) Unlawful possession of oxycodone as described in ORS 475.834;

(f) Unlawful possession of heroin as described in ORS 475.854;

(g) Unlawful possession of marijuana or a marijuana product as described in ORS 475.864;

(h) Unlawful possession of 3,4-methylenedioxymethamphetamine as described in ORS 475.874;

(i) Unlawful possession of cocaine as described in ORS 475.884;

(j) Unlawful possession of methamphetamine as described in ORS 475.894;

(k) Unlawfully possessing a prescription drug as described in ORS 689.527 (6); and

(L) Unlawful possession of drug paraphernalia with intent to sell or deliver as described in ORS 475.525.

(4)(a) A person may not be arrested for violating, or found to be in violation of, the conditions of the person's pretrial release, probation, post-prison supervision or parole if the violation involves:

(A) The possession or use of a controlled substance or frequenting a place where controlled substances are used; and

(B) The evidence of the violation was obtained because the person contacted emergency medical services or a law enforcement agency to obtain medical assistance for another person who needed medical assistance due to a drug-related overdose.

(b) A person may not be arrested for violating, or found to be in violation of, the conditions of the person's pretrial release, probation, post-prison supervision or parole if the violation involves:

(A) The possession or use of a controlled substance or frequenting a place where controlled substances are used; and

(B) The evidence of the violation was obtained because the person was in need of medical assistance due to a drug-related overdose and any person contacted emergency medical services or a law enforcement agency to obtain medical assistance for the person.

(5)(a) A person may not be arrested on an outstanding warrant for any of the offenses listed in subsection (3) of this section, or on an outstanding warrant for a violation, other than commission of a new crime, of the conditions of the person's probation, post-prison supervision or parole for conduct that would constitute an offense listed in subsection (3) of this section, if the location of the person was obtained because the person contacted emergency medical services or a law enforcement agency to obtain medical assistance for another person who needed medical assistance due to a drug-related overdose.

(b) A person may not be arrested on an outstanding warrant for any of the offenses listed in subsection (3) of this section, or on an outstanding warrant for a violation, other than commission of a new crime, of the conditions of the person's probation, post-prison supervision or parole for conduct that would constitute an offense listed in subsection (3) of this section, if the location of the person was obtained because the person was in need of medical assistance due

to a drug-related overdose and any person contacted emergency medical services or a law enforcement agency to obtain medical assistance for the person.

(c) This subsection does not apply to outstanding federal warrants or outstanding warrants issued from other states.

(6) The immunity from arrest and prosecution described in this section is not grounds for the suppression of evidence relating to a criminal offense other than the offenses listed in subsection (3) of this section.

(7) As used in this section:

(a) "Controlled substance" has the meaning given that term in ORS 475.005.

(b) "Drug-related overdose" means an acute condition, including mania, hysteria, extreme physical illness, coma or death, resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, that a person would reasonably believe to be a condition that requires medical attention. [2015 c.274 §1]

Note: 475.898 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.900 Crime category classification; proof of commercial drug offense. (1) A violation of ORS 475.752, 475.806 to 475.894, 475.904 or 475.906 shall be classified as crime category 8 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if:

(a) The violation constitutes delivery or manufacture of a controlled substance and involves substantial quantities of a controlled substance. For purposes of this paragraph, the following amounts constitute substantial quantities of the following controlled substances:

(A) Five grams or more of a mixture or substance containing a detectable amount of heroin;

(B) Ten grams or more of a mixture or substance containing a detectable amount of cocaine;

(C) Ten grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers or salts of its isomers;

(D) Two hundred or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide;

(E) Sixty grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin; or

(F) Five grams or more or 25 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(i) 3,4-methylenedioxyamphetamine;

(ii) 3,4-methylenedioxymethamphetamine; or

(iii) 3,4-methylenedioxy-N-ethylamphet- amine.

(b) The violation constitutes possession, delivery or manufacture of a controlled substance and the possession, delivery or manufacture is a commercial drug offense. A possession, delivery or manufacture is a commercial drug offense for purposes of this subsection if it is accompanied by at least three of the following factors:

(A) The delivery was of heroin, cocaine, methamphetamine, lysergic acid diethylamide, psilocybin or psilocin and was for consideration;

(B) The offender was in possession of $300 or more in cash;

(C) The offender was unlawfully in possession of a firearm or other weapon as described in ORS 166.270 (2), or the offender used, attempted to use or threatened to use a deadly or dangerous weapon as defined in ORS 161.015, or the offender was in possession of a firearm or other deadly or dangerous weapon as defined in ORS 161.015 for the purpose of using it in connection with a controlled substance offense;

(D) The offender was in possession of materials being used for the packaging of controlled substances such as scales, wrapping or foil, other than the material being used to contain the substance that is the subject of the offense;

(E) The offender was in possession of drug transaction records or customer lists;

(F) The offender was in possession of stolen property;

(G) Modification of structures by painting, wiring, plumbing or lighting to facilitate a controlled substance offense;

(H) The offender was in possession of manufacturing paraphernalia, including recipes, precursor chemicals, laboratory equipment, lighting, ventilating or power generating equipment;

(I) The offender was using public lands for the manufacture of controlled substances;

(J) The offender had constructed fortifications or had taken security measures with the potential of injuring persons; or

(K) The offender was in possession of controlled substances in an amount greater than:

(i) Three grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) Eight grams or more of a mixture or substance containing a detectable amount of cocaine;

(iii) Eight grams or more of a mixture or substance containing a detectable amount of methamphetamine;

(iv) Twenty or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide;

(v) Ten grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin; or

(vi) Four grams or more or 20 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(I) 3,4-methylenedioxyamphetamine;

(II) 3,4-methylenedioxymethamphetamine; or

(III) 3,4-methylenedioxy-N-ethylamphet:HYP amine.

(c) The violation constitutes a violation of ORS 475.848, 475.852, 475.862, 475.868, 475.872, 475.878, 475.882, 475.888, 475.892 or 475.904.

(d) The violation constitutes manufacturing methamphetamine and the manufacturing consists of:

(A) A chemical reaction involving one or more precursor substances for the purpose of manufacturing methamphetamine; or

(B) Grinding, soaking or otherwise breaking down a precursor substance for the purpose of manufacturing methamphetamine.

(e) The violation constitutes a violation of ORS 475.906 (1) or (2) that is not described in ORS 475.907.

(2) A violation of ORS 475.752 or 475.806 to 475.894 shall be classified as crime category 6 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if:

(a) The violation constitutes delivery of heroin, cocaine, methamphetamine or 3,4-methylenedioxyamphetamine, 3,4-methylenedioxymethamphetamine or 3,4-methylenedioxy-N-ethylamphetamine and is for consideration.

(b) The violation constitutes possession of:

(A) Five grams or more of a mixture or substance containing a detectable amount of heroin;

(B) Ten grams or more of a mixture or substance containing a detectable amount of cocaine;

(C) Ten grams or more of a mixture or substance containing a detectable amount of methamphetamine;

(D) Two hundred or more user units of a mixture or substance containing a detectable amount of lysergic acid diethylamide;

(E) Sixty grams or more of a mixture or substance containing a detectable amount of psilocybin or psilocin; or

(F) Five grams or more or 25 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of:

(i) 3,4-methylenedioxyamphetamine;

(ii) 3,4-methylenedioxymethamphetamine; or

(iii) 3,4-methylenedioxy-N-ethylamphet:HYP amine.

(3) Any felony violation of ORS 475.752 or 475.806 to 475.894 not contained in subsection (1) or (2) of this section shall be classified as:

(a) Crime category 4 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if the violation involves delivery or manufacture of a controlled substance; or

(b) Crime category 1 of the sentencing guidelines grid of the Oregon Criminal Justice Commission if the violation involves possession of a controlled substance.

(4) In order to prove a commercial drug offense, the state shall plead in the accusatory instrument sufficient factors of a commercial drug offense under subsections (1) and (2) of this section. The state has the burden of proving each factor beyond a reasonable doubt.

(5) As used in this section, "mixture or substance" means any mixture or substance, whether or not the mixture or substance is in an ingestible or marketable form at the time of the offense. [Formerly 475.996; 2007 c.494 §1; 2013 c.649 §1; 2015 c.614 §126]

475.902 Directives to Oregon Criminal Justice Commission. (1) The Oregon Criminal Justice Commission shall classify causing another person to ingest a controlled substance as a person felony and crime category 8 of the sentencing guidelines grid of the commission.

(2) The Oregon Criminal Justice Commission shall classify causing another person to ingest a controlled substance with the intent of committing or facilitating a crime of violence against the other person as a person felony and crime category 9 of the sentencing guidelines grid of the commission.

(3) The Oregon Criminal Justice Commission shall amend its rules and appendices to prohibit persons convicted of manufacturing substantial quantities of methamphetamine, its salts, isomers or salts of its isomers from being eligible for an optional probation sentence.

(4) As used in subsection (3) of this section, "substantial quantities" means that quantity of methamphetamine, its salts, isomers or salts of its isomers described in ORS 475.900 (1)(a). [Formerly 475.998; 2009 c.11 §70]

Note: 475.902 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.904 Unlawful manufacture or delivery of controlled substance within 1,000 feet of school; exceptions. (1) Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to manufacture or deliver a schedule I, II or III controlled substance within 1,000 feet of the real property comprising a public or private elementary, secondary or career school attended primarily by minors.

(2) Unlawful manufacture or delivery of a controlled substance within 1,000 feet of a school is a Class A felony.

(3) This section does not apply to:

(a) A licensee or licensee representative, as those terms are defined in ORS 475B.015, that is engaged in lawful activities; or

(b) A person acting within the scope of and in compliance with ORS 475B.245. [Formerly 475.999; 2015 c.614 §127]

475.906 Penalties for unlawful delivery to minors. Except as authorized by ORS 475.005 to 475.285 and 475.752 to 475.980, it is unlawful for any person to deliver a controlled substance to a person under 18 years of age. Any person who violates this section with respect to:

(1) A controlled substance in Schedule I or II, is guilty of a Class A felony.

(2) A controlled substance in Schedule III, is guilty of a Class B felony.

(3) A controlled substance in Schedule IV, is guilty of a Class A misdemeanor.

(4) A controlled substance in Schedule V, is guilty of a Class B misdemeanor. [Formerly 475.995]

475.907 Sentencing for unlawful delivery of cocaine, methamphetamine, heroin or ecstasy to minors. (1) When a person is convicted of the unlawful delivery of cocaine, methamphetamine, heroin or ecstasy to a person under 18 years of age, the court shall sentence the person to a term of incarceration ranging from 34 months to 72 months, depending on the person's criminal history.

(2) The sentence described in subsection (1) of this section does not apply to a person who is less than three years older than the person under 18 years of age to whom the controlled substance was delivered, unless the person has a previous conviction for delivery of cocaine, methamphetamine, heroin or ecstasy to a person under 18 years of age. [2008 c.14 §3]

Note: 475.907, 475.924 and 475.925 were enacted into law but were not added to or made a part of ORS chapter 475 or any series therein by law. See Preface to Oregon Revised Statutes for further explanation.

475.908 Causing another person to ingest a controlled substance. (1) A person commits the crime of causing another person to ingest a controlled substance if the person knowingly or intentionally causes the other person to ingest, other than by administering or dispensing, a controlled substance or a controlled substance analog without consent of the other person. A person who violates this subsection is guilty of a Class B felony.

(2) Notwithstanding subsection (1) of this section, causing another person to ingest a controlled substance is a Class A felony if the person, with the intent of committing or facilitating a crime of violence against the other person, knowingly or intentionally causes the other person to ingest a controlled substance or a controlled substance analog without consent of the other person.

(3) For the purposes of this section:

(a)(A) Except as provided in subparagraph (B) of this paragraph, "controlled substance analog" means a substance that:

(i) Has a chemical structure that is substantially similar to the chemical structure of a controlled substance in Schedule I or II.

(ii) Has a stimulant, depressant or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II.

(B) "Controlled substance analog" does not include:

(i) A controlled substance;

(ii) Any substance that has an approved drug application;

(iii) Any substance exempted under 21 U.S.C. 355 if the ingestion is within the scope of investigation authorized under 21 U.S.C. 355; or

(iv) Distilled spirits, wine or malt beverages.

(b) "Crime of violence" means:

(A) Rape in the first degree, as defined in ORS 163.375;

(B) Sodomy in the first degree, as defined in ORS 163.405;

(C) Unlawful sexual penetration in the first degree, as defined in ORS 163.411;

(D) Sexual abuse in the first degree, as defined in ORS 163.427;

(E) Kidnapping in the first degree, as defined in ORS 163.235;

(F) Kidnapping in the second degree, as defined in ORS 163.225;

(G) Assault in the first degree, as defined in ORS 163.185; or

(H) Assault in the second degree, as defined in ORS 163.175.

(c) "Ingest" means to consume or otherwise deliver a controlled substance into the body of a person, except that "ingest" does not include inhalation of marijuana smoke. [Formerly 475.984]

475.910 Application of controlled substance to the body of another person; prohibition. (1) Except as authorized by ORS 475.005 to 475.285 or 475.752 to 475.980, it is unlawful for any person to intentionally apply a controlled substance to the body of another person by injection, inhalation, ingestion or any other means if the other person is under 18 years of age. A person who violates this section with respect to:

(a) A controlled substance in Schedule I or II, is guilty of a Class A felony classified as crime category 9 of the sentencing guidelines grid of the Oregon Criminal Justice Commission.

(b) A controlled substance in Schedule III, is guilty of a Class B felony classified as crime category 8 of the sentencing guidelines grid of the Oregon Criminal Justice Commission.

(c) A controlled substance in Schedule IV, is guilty of a Class C felony.

(d) A controlled substance in Schedule V, is guilty of a Class A misdemeanor.

(2) It is a defense to a charge of violating subsection (1) of this section by applying marijuana that the person applying the marijuana was less than three years older than the victim at the time of the alleged offense. [Formerly 475.986]

475.912 Unlawful delivery of imitation controlled substance. (1) A person commits the crime of unlawful delivery of an imitation controlled substance if the person knowingly:

(a) Delivers, other than by administering or dispensing, a substance that is not a controlled substance upon the express or implied representation that the substance is a controlled substance; or

(b) Delivers a substance that is not a controlled substance upon the express or implied representation that the substance is of such nature or appearance that the recipient of the delivery will be able to distribute the substance as a controlled substance.

(2) As used in this section, "deliver" or "delivery" means the actual or constructive transfer, or offer or agreement to transfer, from one person to another of a substance, whether or not there is an agency relationship.

(3) Unlawful delivery of an imitation controlled substance is a Class A misdemeanor. [Formerly 475.991]

475.914 Prohibited acts for registrants; penalties. (1) It is unlawful for any person:

(a) Who is subject to ORS 475.095 and 475.125 to 475.185 to deliver or dispense a controlled substance in violation of ORS 475.185;

(b) Who is a registrant, to manufacture a controlled substance not authorized by this registration, or to deliver or dispense a controlled substance not authorized by the registration to another registrant or other authorized person;

(c) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under ORS 475.005 to 475.285 and 475.752 to 475.980;

(d) To refuse an entry into any premises for any inspection authorized by ORS 475.005 to 475.285 and 475.752 to 475.980; or

(e) To keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft or other structure or place, while knowingly permitting persons to use controlled substances in such places in violation of ORS 475.005 to 475.285 and 475.752 to 475.980, or which is used for keeping or selling them in violation of ORS 475.005 to 475.285 and 475.752 to 475.980.

(2) Any person who violates this section with respect to:

(a) A controlled substance in Schedule I, is guilty of a Class C felony.

(b) A controlled substance in Schedule II, is guilty of a Class A misdemeanor.

(c) A controlled substance in Schedule III, is guilty of a Class B misdemeanor.

(d) A controlled substance in Schedule IV or V, is guilty of a Class C misdemeanor. [Formerly 475.993; 2011 c.524 §25]

475.916 Prohibited acts involving records and fraud; penalties. (1) It is unlawful for any person knowingly or intentionally:

(a) To deliver as a registrant a controlled substance classified in Schedule I or II, except pursuant to an order form as required by ORS 475.175;

(b) To use in the course of manufacture or delivery of a controlled substance a registration number which is fictitious, revoked, suspended or issued to another person;

(c) To acquire or to attempt to acquire or obtain or attempt to obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge;

(d) To furnish false or fraudulent material information in, or omit any material information from, any application, report, record or other document required to be kept or filed under ORS 475.005 to 475.285 and 475.752 to 475.980; or

(e) To make, deliver or possess any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

(2) Any person who violates this section is guilty of a Class A misdemeanor. [Formerly 475.994]

475.918 Falsifying drug test results. (1) A person commits the crime of falsifying drug test results if the person intentionally uses, or possesses with intent to use, any substance or device designed to falsify the results of a drug test of the person.

(2) Falsifying drug test results is a Class B misdemeanor.

(3) As used in this section and ORS 475.920, “drug test” means a lawfully administered test designed to detect the presence of a controlled substance. [Formerly 475.981]

475.920 Providing drug test falsification equipment. (1) A person commits the crime of providing drug test falsification equipment if the person intentionally delivers, possesses with intent to deliver or manufactures with intent to deliver a substance or device designed to enable a person to falsify the results of a drug test.

(2) Providing drug test falsification equipment is a Class A misdemeanor. [Formerly 475.982]

475.924 Definitions for ORS 164.061, 475.907, 475.924 and 475.925. As used in ORS 164.061, 475.907, 475.924 and 475.925:

(1) “Controlled substance” means:
(a) Cocaine;
(b) Methamphetamine;
(c) Heroin; or
(d) Ecstasy.
(2) “Ecstasy” means:
(a) 3,4-methylenedioxymethamphetamine;
(b) 3,4-methylenedioxyamphetamine; or
(c) 3,4-methylenedioxy-N-ethylampheta-:LEND
mine.
(3) “Mixture or substance” means any mixture or substance, whether or not the mixture or substance is in an ingestible or marketable form at the time of the offense. [2008 c.14 §5]

Note: See note under 475.907.

475.925 Sentences for certain controlled substance offenses. When a person is convicted of the unlawful delivery or manufacture of a controlled substance, the court shall sentence the person to a term of incarceration ranging from:
(1) 58 months to 130 months, depending on the person’s criminal history, if the delivery or manufacture involves:
(a) 500 grams or more of a mixture or substance containing a detectable amount of cocaine;
(b) 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers or salts of its isomers;
(c) 100 grams or more of a mixture or substance containing a detectable amount of heroin; or
(d) 100 grams or more or 500 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of ecstasy.
(2) 34 months to 72 months, depending on the person’s criminal history, if the delivery or manufacture involves:
(a) 100 grams or more of a mixture or substance containing a detectable amount of cocaine;
(b) 100 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers or salts of its isomers;
(c) 50 grams or more of a mixture or substance containing a detectable amount of heroin; or
(d) 50 grams or more or 250 or more pills, tablets or capsules of a mixture or substance containing a detectable amount of ecstasy. [2008 c.14 §2]

Note: See note under 475.907.

475.930 Imposition of sentence under ORS 164.061, 475.907, 475.924 and 475.925. (1) When a court sentences a person under ORS 164.061, 475.907, 475.924 and 475.925:
(a) The court shall use the criminal history scale of the sentencing guidelines grid of the Oregon Criminal Justice Commission to determine the sentence to impose. The sentence described in:
(A) ORS 475.925 (1) shall be determined utilizing crime category 10 of the sentencing guidelines grid.
(B) ORS 475.907 (1) and 475.925 (2) shall be determined utilizing crime category 9 of the sentencing guidelines grid.
(C) ORS 164.061 shall be determined utilizing crime category 8 of the sentencing guidelines grid.

(b)(A) Notwithstanding ORS 161.605, the court shall impose the sentence described in ORS 164.061, 475.907, 475.924 and 475.925 and may not impose a sentence of optional probation or grant a downward dispositional departure or a downward durational departure under the rules of the commission.

(B) The court may impose a sentence other than the sentence described in ORS 164.061, 475.907, 475.924 and 475.925 if the court imposes a longer term of incarceration that is otherwise required or authorized by law.

(2) A person sentenced under ORS 164.061, 475.907, 475.924 and 475.925 may not receive a reduction in the term of incarceration for appropriate institutional behavior that exceeds 20 percent of the sentence imposed. [2008 c.14 §11]

Note: 475.930 was enacted into law but was not added to or made a part of ORS chapter 475 or any series therein by law. See Preface to Oregon Revised Statutes for further explanation.

475.933 [2009 c.660 §10; repealed by 2013 c.649 §9]

475.934 Sentencing of persons with previous conviction for controlled substance offense. (1) When a court sentences a person convicted of a crime listed in subsection (2) of this section, the court may not impose a sentence of optional probation or grant a downward dispositional departure or a downward durational departure under the rules of the Oregon Criminal Justice Commission if the person has a previous conviction for any of the crimes listed in subsection (2) of this section.

(2) The crimes to which subsection (1) of this section applies are:

(a) Manufacture or delivery of a controlled substance, other than marijuana, under ORS 475.752 (1);

(b) Creation or delivery of a counterfeit substance, other than marijuana, under ORS 475.752 (2);

(c) Manufacture or delivery of heroin under ORS 475.846, 475.848, 475.850 or 475.852;

(d) Manufacture or delivery of 3,4-methylenedioxymethamphetamine under ORS 475.866, 475.868, 475.870 or 475.872;

(e) Manufacture or delivery of cocaine under ORS 475.876, 475.878, 475.880 or 475.882;

(f) Manufacture or delivery of methamphetamine under ORS 475.886, 475.888, 475.890 or 475.892;

(g) Manufacture or delivery of a controlled substance within 1,000 feet of a school under ORS 475.904;

(h) Delivery of a controlled substance to a person under 18 years of age under ORS 475.906; and

(i) Possession of a precursor substance with intent to manufacture a controlled substance under ORS 475.967.

(3)(a) For a crime committed on or after November 1, 1989, a conviction is considered to have occurred upon the pronouncement in open court of sentence. However, when sentences are imposed for two or more convictions arising out of the same conduct or criminal episode, none of the convictions is considered to have occurred prior to any of the other convictions arising out of the same conduct or criminal episode.

(b) For a crime committed prior to November 1, 1989, a conviction is considered to have occurred upon the pronouncement in open court of a sentence or upon the pronouncement in open court of the suspended imposition of a sentence.

(4) For purposes of this section, previous convictions must be proven pursuant to ORS 137.079.

(5) As used in this section, “previous conviction” includes convictions entered in any other state or federal court for comparable offenses. [2013 c.649 §11]

Note: 475.934 becomes operative July 1, 2023, and applies to crimes committed on or after July 1, 2023. See section 12, chapter 649, Oregon Laws 2013.

Note: 475.934 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.935 Presumptive sentences for certain methamphetamine offenses. (1) Except as provided in ORS 475.900, 475.907 or 475.925, when the court sentences a person convicted of delivery of methamphetamine under ORS 475.890 or 475.892, the presumptive sentence is 19 months of incarceration, unless the rules of the Oregon Criminal Justice Commission prescribe a longer presumptive sentence, if the person has two or more previous convictions for any combination of the following crimes:

(a) Delivery or manufacture of methamphetamine under ORS 475.752, 475.886 or 475.890;

(b) Delivery or manufacture of methamphetamine within 1,000 feet of a school under ORS 475.888, 475.892 or 475.904; or

(c) Possession of a precursor substance with intent to manufacture a controlled substance under ORS 475.967.

(2) The court may impose a sentence other than the sentence provided by subsection (1) of this section if the court imposes:

(a) A longer term of incarceration that is otherwise required or authorized by law; or

(b) An upward durational departure sentence that is authorized by law or the rules of the Oregon Criminal Justice Commission based upon findings of substantial and compelling reasons. Unless otherwise authorized by law or rule of the Oregon Criminal Justice Commission, the maximum departure allowed for a person sentenced under this subsection is double the presumptive sentence provided in subsection (1) of this section.

(3) As used in this section, “previous conviction” means:

(a) Convictions occurring before, on or after August 16, 2005; and

(b) Convictions entered in any other state or federal court for comparable offenses.

(4)(a) For a crime committed on or after November 1, 1989, a conviction is considered to have occurred upon the pronouncement of sentence in open court. However, when sentences are imposed for two or more convictions arising out of the same conduct or criminal episode, none of the convictions is considered to have occurred prior to any of the other convictions arising out of the same conduct or criminal episode.

(b) For a crime committed prior to November 1, 1989, a conviction is considered to have occurred upon the pronouncement in open court of a sentence or upon the pronouncement in open court of the suspended imposition of a sentence.

(5) For purposes of this section, previous convictions must be proven pursuant to ORS 137.079. [Formerly 137.721]

Note: 475.935 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

PRECURSOR SUBSTANCES

475.940 Precursor substances described. As used in ORS 475.752 to 475.980:

(1) "Iodine matrix" means iodine at a concentration greater than two percent by weight in a matrix or solution.

(2) "Matrix" means something, as a substance, in which something else originates, develops, or is contained.

(3) "Precursor substance" means:

(a) Phenyl-2-propanone.

(b) Methylamine.

(c) D-lysergic acid.

(d) Ergotamine.

(e) Diethyl Malonate.

(f) Malonic acid.

(g) Ethyl Malonate.

(h) Barbituric acid.

(i) Piperidine.

(j) N-acetylanthranilic acid.

(k) Ethylamine.

(L) Pyrolidine.

(m) Phenylacetic acid.

(n) Anthranilic acid.

(o) Morpholine.

(p) Ephedrine.

(q) Pseudoephedrine.

(r) Norpseudoephedrine.

(s) Phenylpropanolamine.

(t) Benzyl cyanide.

(u) Ergonovine.

(v) 3,4-Methylenedioxyphenyl-2-propanone.

(w) Propionic anhydride.

(x) Insosafrole (Isosafrole).

(y) Safrole.

(z) Piperonal.

(aa) N-methylephedrine.

(bb) N-ethylephedrine.

(cc) N-methylpseudoephedrine.

(dd) N-ethylpseudoephedrine.

(ee) Hydriotic acid.

(ff) Gamma butyrolactone (GBL), including butyrolactone, 1,2-butanolide, 2-oxanol-one, tetrahydro-2-
furanone, dihydro-2(3H)-
furanone and tetramethylene glycol, but not including gamma aminobutyric acid (GABA).

(gg) 1,4-butanediol.

(hh) Any salt, isomer or salt of an isomer of the chemicals listed in paragraphs (a) to (gg) of this subsection.

(ii) Iodine in its elemental form.

(jj) Iodine matrix.

(kk) Red phosphorus, white phosphorus, yellow phosphorus or hypophosphorus acid and its salts.

(LL) Anhydrous ammonia.

(mm) Lithium metal.

(nn) Sodium metal.

(oo) Any substance established as a precursor substance by rule under authority granted in ORS 475.945. [1987 c.657 §§3,3a; 2001 c.615 §1; 2003 c.448 §1; 2005 c.706 §17]

475.945 Authority and duties of Department of State Police; rules. This section grants authority to and establishes duties of the Department of State Police in relation to the requirements concerning precursor substances under ORS 475.752 to 475.980. The following are applicable as described:

(1) The department may adopt rules in accordance with ORS chapter 183 that add substances to those specifically enumerated in ORS 475.940 (3) if the substance is a precursor to a controlled substance. Similarly, the department may delete such substances as it has added by administrative rule.

(2) Notwithstanding the time period established for reporting under ORS 475.950, the department may authorize the submission of such reports on a monthly basis with respect to repeated, regular transactions between the furnisher and recipient involving the same substance if the department determines that all of the following exist:

(a) A pattern of regular supply of such substance exists as between the manufacturer, wholesaler, retailer or other person who sells, transfers or otherwise furnishes such substance and the recipient of the substance.

(b) The recipient has established a record of use of the substance for lawful purposes.

(3) The department shall establish a common form for reporting or recording for purposes of ORS 475.950, 475.975 (3), 475.976 (3) and 475.978 (1). The department may include as information required to be reported or recorded on the form any information the department determines will be convenient or useful to police agencies in finding potentially illegal uses of precursor substances. The reporting or recording form shall require at least the following information:

(a) The name of the substance.

(b) The quantity of the substance sold, transferred or furnished.

(c) The date the substance was sold, transferred or furnished.

(d) The name and address of the person buying or receiving the substance accompanied by a verification of the person's identification by means the department requires by rule.

(e) The name and address of the person selling, transferring or furnishing the substance accompanied by a verification of the person's identification by means the department requires by rule.

(f) The name of any agent acting on behalf of any party to the transaction accompanied by a verification of the person's identification by means the department requires by rule.

(4) The department shall establish a common reporting form for purposes of ORS 475.955. The department may include as information required to be reported on the form any information the department determines will be convenient or useful to police agencies in finding potentially illegal uses of precursor substances. The reporting form shall require at least the following information:

(a) The name of the person making the report.

(b) The name of the common carrier or person who transports the substance and date of shipment of the substance.

(c) The date and circumstances of discovering the loss, theft or discrepancy.

(5) The department shall furnish a copy of the report to the local law enforcement agency in whose jurisdiction the transaction occurred. [1987 c.657 §6; 2001 c.615 §12]

475.947 Warning notice for precursor substance violation. (1) In lieu of making an arrest or issuing a citation, a law enforcement officer may deliver a warning notice to a person or business that the officer has probable cause to believe has sold or otherwise delivered a precursor substance in violation of ORS 475.752 to 475.980 whenever the officer reasonably believes that the public interest will be adequately served under the circumstances by issuance of a written warning notice. The notice must be in substantially the following form:

WARNING NOTICE
Please Read this Notice Carefully!!!

TO: _____(name of person or business)
DATE: _____(date of notice)
FROM: _____(name of law enforcement agency)
RE: _____(name of precursor substance or product)

The undersigned law enforcement officer has probable cause to believe that on _____ (date of violation), you sold or otherwise delivered a quantity of the precursor substance identified above in violation of the laws of the State of Oregon.

This warning notice has been given to you in lieu of formal action concerning that violation. Please be aware that any further violation may result in formal action being taken against you, which may include, but is not limited to, the filing of an action in circuit court seeking a court order prohibiting you from selling or delivering any quantity of one or more precursor substances to any person.

_____
Law Enforcement Officer

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(2) A warning notice issued by a law enforcement officer under subsection (1) of this section shall be personally delivered to the person named in the notice, or personally delivered to the person in charge of the business named in the notice. [2003 c.448 §6]

475.949 Injunctive relief for precursor substance violation. (1) Whenever it appears that any person has repeatedly sold or delivered one or more precursor substances in violation of the provisions of ORS 475.752 to 475.980, the county attorney or city attorney may cause a civil suit to be instituted in the circuit court for injunctive relief to restrain the person from selling or delivering one or more of the precursor substances.

(2) Upon a proper showing, the court may grant a permanent or temporary injunction prohibiting the defendant or defendants from any further sale or delivery of any amount of one or more precursor substances.

(3) The court may decline to enter an injunctive order against a defendant who:

(a) Demonstrates no knowledge of the existence of the violation, or demonstrates reasonable efforts to stop the violation from occurring;

(b) Has not been guilty of any contempt of court in the proceedings; and

(c) The court finds will make best efforts to immediately end any violation that may exist and prevent any further violation from occurring. [2003 c.448 §7]

475.950 Failure to report precursor substances transaction. (1) A person commits the offense of failure to report a precursor substances transaction if the person does any of the following:

(a) Sells, transfers or otherwise furnishes any precursor substance described in ORS 475.940 (3)(a) to (hh) and (oo) and does not, at least three days before delivery of the substance, submit to the Department of State Police a report that meets the reporting requirements established by rule under ORS 475.945.

(b) Receives any precursor substance described in ORS 475.940 (3)(a) to (hh) and (oo) and does not, within 10 days after receipt of the substance, submit to the Department of State Police a report that meets the reporting requirements established by rule under ORS 475.945.

(2) This section does not apply to any of the following:

(a) Any pharmacist or other authorized person who sells or furnishes a precursor substance upon the prescription of a physician licensed under ORS chapter 677, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, dentist or veterinarian.

(b) Any practitioner, as defined in ORS 475.005, who administers or furnishes a precursor substance to patients upon prescription.

(c) Any person licensed by the State Board of Pharmacy who sells, transfers or otherwise furnishes a precursor substance to a licensed pharmacy, physician licensed under ORS chapter 677, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, dentist or veterinarian for distribution to patients upon prescription.

(d) Any person who is authorized by rule under ORS 475.945 to report in an alternate manner if the person complies with the alternate reporting requirements.

(e) Any patient of a practitioner, as defined in ORS 475.005, who obtains a precursor substance from a licensed pharmacist, physician licensed under ORS chapter 677, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, dentist or veterinarian pursuant to a prescription.

(f) Any person who sells or transfers ephedrine, pseudoephedrine or phenylpropanolamine in compliance with ORS 475.973.

(g) Any practitioner, as defined in ORS 475.005, who dispenses a precursor substance to a person with whom the practitioner has a professional relationship.

(h) Any person who obtains a precursor substance from a practitioner, as defined in ORS 475.005, with whom the person has a professional relationship.

(i) Any person who sells or transfers an isomer of a precursor substance, unless it is an optical isomer.

(3) Penalties related to providing false information on a report required under this section are provided under ORS 475.965.

(4) The Department of State Police and any law enforcement agency may inspect and remove copies of the sales records of any retail or wholesale distributor of methyl sulfonyl methane or a precursor substance during the normal business hours of the retail or wholesale distributor or may require the retail or wholesale distributor to provide copies of the records.

(5) Failure to report a precursor substances transaction is a Class A misdemeanor. [1987 c.657 §2; 2001 c.615 §2; 2003 c.448 §2; 2005 c.706 §18; 2007 c.253 §1; 2013 c.129 §33; 2014 c.45 §66]

475.955 Failure to report missing precursor substances. (1) A person commits the offense of failure to report missing precursor substances if the person:

(a) Is a licensee or other person regulated by the provisions of ORS 475.005 to 475.285 and 475.752 to 475.980;

(b) Discovers any theft or loss of any precursor substance or any difference between the quantity received and the quantity shipped; and

(c) Within three days after discovery of the theft or loss or actual knowledge of the discrepancy, does not report the theft, loss or discrepancy to the Department of State Police in the manner provided by rule adopted under ORS 475.945.

(2) Penalties for providing false information on any report required under this section are provided under ORS 465.965.

(3) The offense described in this section, failure to report missing precursor substances, is a Class A misdemeanor. [1987 c.657 §4; 1995 c.440 §34; 2001 c.615 §13]

475.960 Illegally selling drug equipment. (1) A person commits the offense of illegally selling drug equipment if the person sells any substance, article, apparatus or device with knowledge that the substance, article, apparatus or device will be used to manufacture, compound, convert, process or prepare a controlled substance for unlawful sale or distribution.

(2) The offense described in this section, illegally selling drug equipment, is a Class A misdemeanor. [1987 c.657 §5]

475.962 Distribution of equipment, solvent, reagent or precursor substance with intent to facilitate manufacture of controlled substance. (1) A person commits the crime of distribution of equipment, a solvent, a reagent or a precursor substance with intent to facilitate the manufacture of a controlled substance if the person sells or otherwise transfers equipment, a solvent, a reagent or a precursor substance with knowledge that the equipment, solvent, reagent or precursor substance is intended to be used in the manufacture of a controlled substance in violation of ORS 475.752.

(2) Distribution of equipment, a solvent, a reagent or a precursor substance with intent to facilitate the manufacture of a controlled substance is a Class B felony. [2005 c.706 §8]

Note: 475.962 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.965 Providing false information on precursor substances report or record. (1) A person commits the offense of providing false information on a precursor substances report or record if the person knowingly provides false information in any report or record required under ORS 475.950, 475.955, 475.975, 475.976 or 475.978.

(2) The offense described in this section, providing false information on a precursor substances report or record, is a Class A misdemeanor. [1987 c.657 §7; 2001 c.615 §14]

475.967 Possession of precursor substance with intent to manufacture controlled substance. (1) A person commits the crime of possession of a precursor substance with intent to manufacture a controlled substance if the person possesses one or more precursor substances with the intent to manufacture a controlled substance in violation of ORS 475.752 (1), 475.806, 475.808, 475.816, 475.818, 475.826, 475.828, 475.846, 475.848, 475.866, 475.868, 475.876, 475.878, 475.886 or 475.888.

(2) Possession of a precursor substance with intent to manufacture a controlled substance is a Class B felony. [2001 c.615 §10; 2005 c.708 §58; 2011 c.524 §22]

475.969 Unlawful possession of phosphorus. (1) Except as otherwise provided in subsection (2) of this section, a person commits the crime of unlawful possession of phosphorus if the person knowingly possesses any amount of phosphorus.

(2) Subsection (1) of this section does not apply to:

(a) A person who is conducting a licensed business that involves phosphorus in the manufacture of:

(A) The striking surface used for lighting matches;

(B) Flame retardant polymers; or

(C) Fireworks if the person possesses a federal license to manufacture explosives;

(b) A person who possesses phosphorus in conjunction with experiments conducted in a chemistry or chemistry related laboratory maintained by a:

(A) Regularly established public or private secondary school; or

(B) Public or private institution of higher education that is accredited by a regional or national accrediting agency recognized by the United States Department of Education;

(c) A retail distributor, wholesaler, manufacturer, warehouseman or common carrier or an agent of any of these persons, who possesses phosphorus in the regular course of lawful business activities;

(d) The possession of phosphorus as a component of a commercially produced product including, but not limited to, matchbooks, fireworks and emergency flares; or

(e) A person who possesses phosphorus in a chemical compound in the regular course of a lawful agricultural activity.

(3) Unlawful possession of phosphorus is a Class A misdemeanor. [2001 c.615 §4]

475.971 Unlawful possession of anhydrous ammonia. (1) A person commits the crime of unlawful possession of anhydrous ammonia if the person knowingly possesses anhydrous ammonia in a container that is not approved by the United States Department of Transportation to hold anhydrous ammonia nor constructed to meet state and federal health and safety standards to hold anhydrous ammonia.

(2) Unlawful possession of anhydrous ammonia is a Class A misdemeanor.

(3) This section does not apply to a person who possesses anhydrous ammonia as part of a cleanup, as defined in ORS 466.605, of anhydrous ammonia by the Department of Environmental Quality under ORS 466.610. [2001 c.615 §5]

475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records. (1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance. Except as otherwise provided in this paragraph, the State Board of Pharmacy shall adopt rules to classify ephedrine, pseudoephedrine and phenylpropanolamine as Schedule III controlled substances. The Schedule III classification may be modified by the State Board of Pharmacy if the State Board of Pharmacy finds that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine under a Schedule III designation do not significantly reduce the number of methamphetamine laboratories within the state.

(b) Records of transactions involving products containing ephedrine, pseudoephedrine or phenylpropanolamine are subject to inspection by the State Board of Pharmacy and law enforcement agencies. A person required to make or maintain records of transactions involving products containing ephedrine, pseudoephedrine or phenylpropanolamine shall forward the records to the Department of State Police if directed to do so by the department. Failure to forward records as required by this paragraph is a Class A misdemeanor.

(2) This section does not apply to products that the State Board of Pharmacy, upon application of a manufacturer, exempts by rule because the product is formulated to effectively prevent conversion of the active ingredient into methamphetamine or its salts or precursors. Upon notification from the Department of State Police that the department has probable cause to believe that a product exempted under this subsection does not effectively prevent conversion of

the active ingredient into methamphetamine or its salts or precursors, the State Board of Pharmacy may issue an emergency rule revoking the exemption for the product pending a full hearing. [2001 c.615 §6; 2003 c.448 §3; 2005 c.706 §11; 2011 c.524 §26]

475.975 Unlawful possession of iodine in its elemental form; recording transfers; unlawful distribution of iodine in its elemental form. (1) Except as otherwise provided in subsection (2) of this section, a person commits the crime of unlawful possession of iodine in its elemental form if the person knowingly possesses iodine in its elemental form.

(2) Subsection (1) of this section does not apply to:

(a) A physician, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, pharmacist, retail distributor, wholesaler, manufacturer, warehouseman or common carrier or an agent of any of these persons who possesses iodine in its elemental form in the regular course of lawful business activities;

(b) A person who possesses iodine in its elemental form in conjunction with experiments conducted in a chemistry or chemistry related laboratory maintained by a:

(A) Regularly established public or private secondary school;

(B) Public or private institution of higher education that is accredited by a regional or national accrediting agency recognized by the United States Department of Education; or

(C) Manufacturing, government agency or research facility in the course of lawful business activities;

(c) A licensed veterinarian;

(d) A person working in a general hospital who possesses iodine in its elemental form in the regular course of employment at the hospital; or

(e) A person who possesses iodine in its elemental form as a prescription drug pursuant to a prescription issued by a licensed veterinarian, physician, physician assistant licensed under ORS 677.505 to 677.525 or nurse practitioner licensed under ORS 678.375 to 678.390.

(3) Except as otherwise provided in subsection (4) of this section, a person who sells or otherwise transfers iodine in its elemental form to another person shall make a record of each sale or transfer. The record must be made on a form provided by the Department of State Police, completed pursuant to instructions provided by the department and retained by the person for at least three years or sent to the department if directed to do so by the department. Failure to make and retain or send a record required under this subsection is a Class A misdemeanor.

(4) A licensed veterinarian is not required to make a record of a sale or transfer of iodine in its elemental form under subsection (3) of this section if the veterinarian makes a record of the sale or transfer under other applicable laws or rules regarding the prescribing and dispensing of regulated or controlled substances by veterinarians.

(5) A person commits the crime of unlawful distribution of iodine in its elemental form if the person knowingly sells or otherwise transfers iodine in its elemental form to a person not listed in subsection (2) of this section.

(6) Unlawful possession of iodine in its elemental form is a Class A misdemeanor.

(7) Unlawful distribution of iodine in its elemental form is a Class A misdemeanor. [2001 c.615 §7; 2005 c.706 §14; 2014 c.45 §67]

475.976 Unlawful possession of iodine matrix; recording transfers; unlawful distribution of iodine matrix. (1) Except as otherwise provided in subsection (2) of this section, a person commits the crime of unlawful possession of an iodine matrix if the person knowingly possesses an iodine matrix.

(2) Subsection (1) of this section does not apply to:

(a) A person who possesses an iodine matrix as a prescription drug, pursuant to a prescription issued by a licensed veterinarian, physician, physician assistant licensed under ORS 677.505 to 677.525 or nurse practitioner licensed under ORS 678.375 to 678.390;

(b) A person who is actively engaged in the practice of animal husbandry of livestock as defined in ORS 609.125;

(c) A person who possesses an iodine matrix in conjunction with experiments conducted in a chemistry or chemistry related laboratory maintained by a:

(A) Regularly established public or private secondary school;

(B) Public or private institution of higher education that is accredited by a regional or national accrediting agency recognized by the United States Department of Education; or

(C) Manufacturing, government agency or research facility in the course of lawful business activities;

(d) A veterinarian, physician, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, pharmacist, retail distributor, wholesaler, manufacturer, warehouseman or common carrier or an agent of any of these persons who possesses an iodine matrix in the regular course of lawful business activities; or

(e) A person working in a general hospital who possesses an iodine matrix in the regular course of employment at the hospital.

(3) Except as otherwise provided in subsection (4) of this section, a person who sells or otherwise transfers an iodine matrix to another person shall make a record of each sale or transfer. The record must be made on a form provided by the Department of State Police, completed pursuant to instructions provided by the department and retained by the person for at least three years or sent to the department if directed to do so by the department. Failure to make and retain or send a record required under this subsection is a Class A misdemeanor.

(4) A licensed veterinarian is not required to make a record of a sale or transfer of an iodine matrix under subsection (3) of this section if the veterinarian makes a record of the sale or transfer under other applicable laws or rules regarding the prescribing and dispensing of regulated or controlled substances by veterinarians.

(5) A person commits the crime of unlawful distribution of an iodine matrix if the person knowingly sells or otherwise transfers an iodine matrix to a person not listed in subsection (2) of this section.

(6) Unlawful possession of an iodine matrix is a Class A misdemeanor.

(7) Unlawful distribution of an iodine matrix is a Class A misdemeanor. [2001 c.615 §8; 2005 c.706 §15; 2014 c.45 §68]

475.977 Possessing or disposing of methamphetamine manufacturing waste. (1) As used in this section:

(a) “Dispose of” means to discharge, deposit, inject, spill, leak or place methamphetamine manufacturing waste into or onto land or water.

(b) “Methamphetamine manufacturing waste” means chemical waste or debris, used in or resulting from the manufacture of methamphetamine or the grinding, soaking or otherwise breaking down of a precursor substance for the manufacture of methamphetamine.

(2) A person commits the crime of possessing or disposing of methamphetamine manufacturing waste if the person:

(a) Knowingly possesses methamphetamine manufacturing waste; or

(b) Knowingly disposes of methamphetamine manufacturing waste.

(3) Subsection (2) of this section does not apply to the possession or disposal of methamphetamine manufacturing waste if:

(a) The person was storing, treating or disposing of the waste pursuant to state or federal laws regulating the cleanup or disposal of waste products from unlawful methamphetamine manufacturing;

(b) The person has notified a law enforcement agency of the existence of the waste; or

(c) The person possesses or disposes of waste that had previously been disposed of by another person on the person's property in violation of subsection (2) of this section.

(4) Possessing or disposing of methamphetamine manufacturing waste is a Class C felony. [2005 c.706 §6]

475.978 Methyl sulfonyl methane; transfers; records; rules. (1) A person who sells or otherwise transfers more than the amount permitted by administrative rule adopted by the Department of State Police of methyl sulfonyl methane to a person other than a physician, physician assistant licensed under ORS 677.505 to 677.525, nurse practitioner licensed under ORS 678.375 to 678.390, pharmacist, veterinarian, retail distributor, wholesaler, manufacturer, warehouseman or common carrier or an agent of any of these persons shall make a record of each such sale or transfer. The record must be made on a form provided by the department, completed pursuant to instructions provided by the department and retained by the person for at least three years. Failure to make and retain a record required under this subsection is a Class A violation.

(2) The department shall adopt a rule establishing the minimum amount of methyl sulfonyl methane the sale or transfer of which requires a report under subsection (1) of this section. In establishing the minimum amount, the department shall determine an amount that is reasonably designed not to infringe upon legitimate uses of methyl sulfonyl methane but that discourages the use of methyl sulfonyl methane in the illicit production and distribution of methamphetamine.

(3) This section applies to the sale or transfer of bulk methyl sulfonyl methane in its powder form only, and does not apply to the sale or transfer of products containing methyl sulfonyl methane in other forms including, but not limited to, liquids, tablets, capsules not containing methyl sulfonyl methane in pure powder form, ointments, creams, cosmetics, foods and beverages. [2001 c.615 §9; 2003 c.448 §4; 2005 c.706 §16; 2014 c.45 §69]

Note: Section 11, chapter 615, Oregon Laws 2001, provides:

Sec. 11. Until the Department of State Police adopts a rule under section 9 of this 2001 Act [475.978], a person who sells or otherwise transfers two pounds or more of methyl sulfonyl methane shall make the reports required by section 9 of this 2001 Act. [2001 c.615 §11]

475.979 Unlawful possession of lithium metal or sodium metal. (1) Except as otherwise provided in subsection (2) of this section, a person commits the crime of unlawful possession of lithium metal or sodium metal if the person knowingly possesses lithium metal or sodium metal.

(2) Subsection (1) of this section does not apply to:

(a) A person who is conducting a lawful manufacturing operation that involves the use of lithium metal or sodium metal;

(b) A person who possesses lithium metal or sodium metal in conjunction with experiments conducted in a chemistry or chemistry related laboratory maintained by a:

(A) Regularly established public or private secondary school; or

(B) Public or private institution of higher education that is accredited by a regional or national accrediting agency recognized by the United States Department of Education;

(c) A retail distributor, wholesaler, manufacturer, warehouseman or common carrier, or an agent of any of these persons, who possesses lithium metal or sodium metal in the regular course of lawful business activities; or

(d) A person who possesses lithium metal or sodium metal as a component of a commercially produced product including, but not limited to, rechargeable batteries.

(3) Unlawful possession of lithium metal or sodium metal is a Class A misdemeanor. [2005 c.706 §9]

Note: 475.979 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 475 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

475.980 Affirmative defense to ORS 475.969, 475.971, 475.975 (1) and 475.976 (1). It is an affirmative defense to a charge of violating ORS 475.969, 475.971, 475.975 (1) or 475.976 (1) that the person possessed the precursor substance for a lawful purpose. [2001 c.615 §17]

475.981 [2001 c.700 §2; renumbered 475.918 in 2005]

475.982 [2001 c.700 §3; renumbered 475.920 in 2005]

475.984 [2001 c.510 §2; renumbered 475.908 in 2005]

475.986 [2001 c.857 §2; renumbered 475.910 in 2005]

475.990 [1957 c.587 §11; 1969 c.310 §4; repealed by 1977 c.745 §45]

475.991 [1981 c.859 §2; renumbered 475.912 in 2005]

475.992 [1977 c.745 §15; 1979 c.777 §55; 1989 c.1075 §3; 1991 c.329 §1; 1991 c.460 §§4,20; 1991 c.818 §5; 1995 c.440 §35; 2005 c.708 §39; renumbered 475.840 in 2005]

475.993 [1977 c.745 §16; 1995 c.440 §36; renumbered 475.914 in 2005]

475.994 [1977 c.745 §17; 1993 c.571 §25; 1995 c.440 §37; renumbered 475.916 in 2005]

475.995 [1977 c.745 §20; 1979 c.777 §56; 1995 c.440 §38; 2005 c.708 §40; renumbered 475.906 in 2005]

475.996 [1991 c.690 §§1,2,3,3a; 2001 c.804 §2; 2001 c.870 §9; 2003 c.695 §3; 2005 c.708 §7; renumbered 475.900 in 2005]

475.997 [1977 c.636 §9; repealed by 1993 c.571 §30]

475.998 [Subsections (1) and (2) of 2001 Edition enacted as 2001 c.510 §3; subsections (3) and (4) of 2001 Edition enacted as 2001 c.804 §1; renumbered 475.902 in 2005]

475.999 [1989 c.806 §2; 1991 c.574 §1; 1993 c.78 §1; 1995 c.343 §49; 1995 c.440 §39; 2005 c.22 §349; 2005 c.708 §41; renumbered 475.904 in 2005]

Chapter 689 — Pharmacists; Drug Outlets; Drug Sales, Occupations and Professions

2015 EDITION

GENERAL PROVISIONS

689.005 Definitions. As used in this chapter:

(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 practitioner's authorized agent; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Approved continuing pharmacy education program" means those seminars, classes, meetings, workshops and other educational programs on the subject of pharmacy approved by the board.

(3) "Board of pharmacy" or "board" means the State Board of Pharmacy.

(4) "Clinical pharmacy agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician as defined in ORS 677.010 that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(5) "Continuing pharmacy education" means:

(a) Professional, pharmaceutical post-graduate education in the general areas of socio-economic and legal aspects of health care;

(b) The properties and actions of drugs and dosage forms; and

(c) The etiology, characteristics and therapeutics of the disease state.

(6) "Continuing pharmacy education unit" means the unit of measurement of credits for approved continuing education courses and programs.

(7) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device other than by administration from one person to another, whether or not for a consideration.

(8) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

(9) "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.

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

(11) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in a human or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

(12) “Drug order” means a written order, in a hospital or other inpatient care facility, for an ultimate user of any drug or device issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, that is immediately reduced to writing by a pharmacist, licensed nurse or other practitioner.

(13) “Drug outlet” means any pharmacy, nursing home, shelter home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.

(14) “Drug room” means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.

(15) “Electronically transmitted” or “electronic transmission” means a communication sent or received through technological apparatuses, including computer terminals or other equipment or mechanisms linked by telephone or microwave relays, or any similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

(16) “Hormonal contraceptive patch” means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.

(17) “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.

(18) “Intern” means a person who is enrolled in or has completed a course of study at a school or college of pharmacy approved by the board and who is licensed with the board as an intern.

(19) “Internship” means a professional experiential program approved by the board under the supervision of a licensed pharmacist registered with the board as a preceptor.

(20) “Itinerant vendor” means a person who sells or distributes nonprescription drugs by passing from house to house, or by haranguing the people on the public streets or in public places, or who uses the customary devices for attracting crowds, recommending their wares and offering them for sale.

(21) “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 nonprescription drug or commercially packaged legend drug or device.

(22) “Manufacture” means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the

preparation or compounding of a drug by an individual for their own use or the preparation, compounding, packaging or labeling of a drug:

(a) By a practitioner as an incident to administering or dispensing of a drug in the course of professional practice; or

(b) By a practitioner or by the practitioner's authorization under supervision of the practitioner for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

(23) "Manufacturer" means a person engaged in the manufacture of drugs.

(24) "Nonprescription drug outlet" means shopkeepers and itinerant vendors registered under ORS 689.305.

(25) "Nonprescription drugs" means drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

(26) "Person" means an individual, corporation, partnership, association or any other legal entity.

(27) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

(28) "Pharmacy" means a place that meets the requirements of rules of the board, is licensed and approved by the board where the practice of pharmacy may lawfully occur and includes apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and prescription laboratories but does not include a place used by a manufacturer or wholesaler.

(29) "Pharmacy technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the board.

(30) "Practice of clinical pharmacy" means:

(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

(31) "Practice of pharmacy" means:

(a) The interpretation and evaluation of prescription orders;

(b) The compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices;

(c) The prescribing and administering of vaccines and immunizations and the providing of patient care services pursuant to ORS 689.645;

(d) The administering of drugs and devices to the extent permitted under ORS 689.655;

(e) The participation in drug selection and drug utilization reviews;

(f) The proper and safe storage of drugs and devices and the maintenance of proper records therefor;

(g) The responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices;

(h) The monitoring of therapeutic response or adverse effect to drug therapy;

(i) The optimizing of drug therapy through the practice of clinical pharmacy;

(j) Patient care services, including medication therapy management and comprehensive medication review;

(k) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy; and

(L) The prescribing and dispensing of hormonal contraceptive patches and self-administered oral hormonal contraceptives pursuant to ORS 689.683.

(32) "Practitioner" means a person licensed and operating within the scope of such license to prescribe, 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 if the person does not reside in Oregon and is registered under the federal Controlled Substances Act.

(33) "Preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of a licensed intern.

(34) "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.

(35) "Prescription" or "prescription drug order" means a written, oral or electronically transmitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use of a drug. When the context requires, "prescription" also means the drug prepared under such written, oral or electronically transmitted direction.

(36) "Retail drug outlet" means a place used for the conduct of the retail sale, administering or dispensing or compounding of drugs or chemicals or for the administering or dispensing of prescriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully occur.

(37) "Self-administered oral hormonal contraceptive" means a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

(38) "Shopkeeper" means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.

(39) "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. Each unit dose container must bear a separate label, be labeled with 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.

(40) "Wholesale drug outlet" means any person who imports, stores, distributes or sells for resale any drugs including legend drugs and nonprescription drugs. [1979 c.777 §5; 1983 c.402 §1; 1985 c.565 §94; 1987 c.108 §1; 1989 c.608 §1; 1991 c.682 §1; 1993 c.272 §1; 1993 c.571 §1; 1997 c.729 §1; 1999 c.350 §2; 2001 c.623 §6; 2005 c.313 §11; 2009 c.326 §1; 2009 c.756 §71; 2011 c.245 §2; 2015 c.362 §3; 2015 c.649 §4]

689.010 [Amended by 1963 c.586 §1; 1967 c.629 §1; 1969 c.514 §1; 1973 c.743 §1; 1975 c.369 §1; 1975 c.686 §8; 1979 c.785 §7; repealed by 1977 c.842 §2 and 1979 c.777 §59]

689.015 [1979 c.777 §4; 1999 c.350 §3; repealed by 2009 c.326 §2]

689.025 Policy; purpose. (1) The practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare and is subject to

regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in the State of Oregon. This chapter shall be liberally construed to carry out these objects and purposes.

(2) It is the purpose of this chapter to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease. [1979 c.777 §§2,3; 1985 c.565 §95; 2007 c.438 §1]

689.035 Short title. This chapter shall be known as the "Oregon Pharmacy Act." [1979 c.777 §1; 1985 c.565 §96]

689.045 Severability. If any provision of ORS 167.203, 414.325, 430.405, 435.010, 453.025, 475.005, 475.135, 475.185, 475.752, 475.906 and 616.855 and ORS chapter 689 is declared unconstitutional or illegal, or the applicability of ORS 167.203, 414.325, 430.405, 435.010, 453.025, 475.005, 475.135, 475.185, 475.752, 475.906 and 616.855 and ORS chapter 689 to any person or circumstances is held invalid by a court of competent jurisdiction, the constitutionality or legality of the remaining provisions of ORS 167.203, 414.325, 430.405, 435.010, 453.025, 475.005, 475.135, 475.185, 475.752, 475.906 and 616.855 and ORS chapter 689 and the application of ORS 167.203, 414.325, 430.405, 435.010, 453.025, 475.005, 475.135, 475.185, 475.752, 475.906 and 616.855 and ORS chapter 689 to other persons and circumstances shall not be affected and shall remain in full force and effect without the invalid provision or application. [1979 c.777 §63; 1999 c.605 §6; 1999 c.1051 §137]

Note: 689.045 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 689 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

689.110 [Amended by 1963 c.586 §2; 1965 c.580 §4; 1967 c.159 §1; 1969 c.514 §2; repealed by 1977 c.842 §45 and 1979 c.777 §59]

STATE BOARD OF PHARMACY

689.115 Membership; qualifications; term; vacancy; compensation. (1) The State Board of Pharmacy consists of nine members appointed by the Governor and subject to confirmation by the Senate in the manner provided in ORS 171.562 and 171.565. All members of the board must be residents of this state. Of the members of the board:

(a) Five must be licensed pharmacists.

(b) Two must be licensed pharmacy technicians.

(c) Two must be members of the public who are not licensed pharmacists or a spouse, domestic partner, child, parent or sibling of a pharmacist.

(2)(a) Board members required to be licensed pharmacists may be selected by the Governor from a list of three to five nominees for each vacancy, submitted by a task force assembled by the Oregon State Pharmacy Association to represent all of the interested pharmacy groups.

(b) The licensed pharmacy technician members of the board must, at the time of appointment:

(A) Be licensed and in good standing to perform the duties of a pharmacy technician in this state;

(B) Be engaged in the performance of the duties of a pharmacy technician in this state; and

(C) Have at least three years of experience in performing the duties of a pharmacy technician in this state after licensure.

(c) The public members of the State Board of Pharmacy must be individuals who:

(A) Have attained the age of majority;

(B) Are not current or former members of the profession of pharmacy;

(C) Do not have and have never had any material financial interest in the providing of pharmacy service; and

(D) Have not engaged in any activity directly related to the practice of pharmacy.

(d) The licensed pharmacist members of the board must at the time of their appointment:

(A) Be licensed and in good standing to engage in the practice of pharmacy in this state;

(B) Be engaged in the practice of pharmacy in this state; and

(C) Have five years of experience in the practice of pharmacy in this state after licensure.

(e) In selecting the members of the board, the Governor shall strive to balance the representation on the board according to:

(A) Geographic areas of this state; and

(B) Ethnic group.

(3)(a) The term of office of each member is four years, but a member serves at the pleasure of the Governor. The terms must be staggered so that no more than three terms end each year. A member is eligible for reappointment. The Governor shall fill vacancies which occur by expiration of full terms within 90 days prior to each date of expiration, and shall fill vacancies which occur for any other reason within 60 days after each such vacancy occurs, for the unexpired term.

(b) A board member shall be removed immediately from the board if, during the member's term, the member:

(A) Is not a resident of this state;

(B) Has been absent from three consecutive board meetings, unless at least one absence is excused;

(C) Is not a licensed pharmacist or a retired pharmacist who was a licensed pharmacist in good standing at the time of retirement, if the board member was appointed to serve on the board as a pharmacist; or

(D) Ceases to be a licensed pharmacy technician, if the board member was appointed to serve on the board as a pharmacy technician.

(4) Members of the board are entitled to compensation and expenses as provided in ORS 292.495. The board may provide by rule for compensation to board members for the performance of official duties at a rate that is greater than the rate provided in ORS 292.495. [1979 c.777 §§7,8,9,11; 1987 c.108 §2; 2009 c.535 §29; 2015 c.284 §1]

Note: Section 2, chapter 284, Oregon Laws 2015, provides:

Sec. 2. The Governor shall appoint the licensed pharmacy technicians as required under ORS 689.115 (1)(b), as amended by section 1 of this 2015 Act, to the State Board of Pharmacy for terms beginning on January 1, 2016. [2015 c.284 §2]

689.120 [Amended by 1967 c.159 §2; repealed by 1969 c.514 §57]

689.125 [1979 c.777 §§10,12; 1985 c.565 §97; repealed by 2009 c.535 §30 and 2009 c.756 §73]

689.130 [Repealed by 1969 c.514 §57]

689.135 General powers of board; fees. (1) The State Board of Pharmacy shall exercise the duties, powers and authority necessary to enforce this chapter and to enforce board rules adopted pursuant to this chapter, including but not limited to the following:

(a) Annual printing and circulation of copies of any changes in the laws relating to pharmacy, controlled substances, drugs and poisons and the rules adopted to enforce the laws, and establishment of reasonable charges for the copies.

(b) Appointment of advisory committees.

(2) The board may join professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board.

(3) In addition to any statutory requirements, the board may require surety bonds as it deems necessary to guarantee the performance and discharge of the duties of any officer or employee receiving and disbursing funds.

(4) The executive director of the board shall keep the seal of the board and shall affix it only in the manner prescribed by the board.

(5) The board shall determine within 30 days prior to the beginning of each state fiscal year the fees to be collected for:

(a) Examinations and reexaminations.

(b) A pharmacist license.

(c) A pharmacist license acquired through reciprocity.

(d) An intern license.

(e) A duplicate pharmacist certificate.

(f) Late renewal of a pharmacist license.

(g) Certification of an approved provider of continuing education courses.

(h) Registration of a drug outlet other than a pharmacy and renewal of the registration.

(i) Initial registration of a pharmacy or an institutional drug outlet.

(j) Annual renewal of a pharmacy or an institutional drug outlet registration.

(k) Late renewal of a pharmacy or an institutional drug outlet registration.

(L) Registration of a nonprescription drug outlet.

(m) Late renewal of a nonprescription drug outlet registration.

(n) Reinspection.

(o) Late renewal of registration of a drug outlet, other than a pharmacy or an institutional drug outlet.

(6) All moneys received under ORS 435.010 to 435.130 and 453.185 and this chapter shall be paid into the State Treasury and placed to the credit of the State Board of Pharmacy Account to be used only for the administration and enforcement of ORS 435.010 to 435.130 and this chapter.

(7) The board may receive and expend funds, in addition to its biennial appropriation, from parties other than the state, provided:

(a) The moneys are awarded for the pursuit of a specific objective that the board is authorized to accomplish by this chapter, or that the board is qualified to accomplish by reason of its jurisdiction or professional expertise;

(b) The moneys are expended for the pursuit of the objective for which they are awarded;

(c) Activities connected with or occasioned by the expenditures of the funds do not interfere with or impair the performance of the board's duties and responsibilities and do not conflict with the exercise of the board's powers as specified by this chapter;

(d) The moneys are kept in a separate, special state account; and

(e) Periodic reports are made to the Governor concerning the board's receipt and expenditure of the moneys.

(8) The board may assign to each drug outlet under its jurisdiction, a uniform state number, coordinated where possible with all other states that adopt the same uniform numbering system.

(9) The board or its authorized representatives shall have the power to investigate and gather evidence concerning alleged violations of the provisions of this chapter or of the rules of the board.

(10) The president and vice president of the board may administer oaths in connection with the duties of the board.

(11) The books, registers and records of the board as made and kept by the executive director, or under the supervision of the executive director, subject to the direction of the board, are prima facie evidence of the matter recorded in the books, registers and records, in any court of law.

(12) The board may administer oaths, issue notices and subpoenas in the name of the board, enforce subpoenas in the manner authorized by ORS 183.440, hold hearings and perform such other acts as are reasonably necessary to carry out its duties under this chapter.

(13)(a) Notwithstanding anything in this chapter to the contrary, whenever a duly authorized representative of the board finds or has probable cause to believe that any drug or device is adulterated, misbranded or a new drug, as defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act, for which there is no approval in effect pursuant to Section 505(b) of the federal Act nor an approved notice of claimed investigational exemption pursuant to Section 505(i) of the federal Act, or otherwise rendered unsafe for use as a result of fire, flood or other natural disaster, the representative shall affix to such drug or device a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated, misbranded, or otherwise rendered unsafe and has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board, its agent or the court. No person shall remove or dispose of such embargoed drug or device by sale or otherwise without the permission of the board or its agent or, after summary proceedings have been instituted, without permission from the court.

(b) When a drug or device detained or embargoed under paragraph (a) of this subsection has been declared by such representative to be adulterated, misbranded or a new drug, or rendered unsafe, the board shall, as soon as practical thereafter, petition the judge of the circuit court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the drug or device so detained or embargoed is not adulterated or misbranded or rendered unsafe, the board shall direct the immediate removal of the tag or other marking.

(c) If the court finds the detained or embargoed drug or device is adulterated or misbranded or rendered unsafe, such drug or device, after entry of the judgment, shall be destroyed at the expense of the owner under the supervision of a board representative and all court costs and fees, storage and other proper expense shall be borne by the owner of such drug or device. When the adulteration or misbranding can be corrected by proper labeling or processing of the drug or device, the court, after entry of the judgment and after such costs, fees and expenses have been paid and a good and sufficient bond has been posted, may direct that such drug or device be delivered to the owner thereof for such labeling or processing under the supervision of a board representative. Expense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of the drug or device on representation to the court by the board that the drug or device is no longer in violation of the embargo and the expense of supervision has been paid.

(d) It is the duty of the Attorney General to whom the board reports any violation of this subsection to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subsection shall be construed to

require the board to report violations whenever the board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

(14) Except as otherwise provided to the contrary, the board shall exercise all of its duties, powers and authority in accordance with ORS chapter 183. [1979 c.777 §20; 1981 c.277 §2; 1983 c.402 §2; 1985 c.565 §98; 1987 c.108 §3; 1991 c.460 §9; 1993 c.571 §3; 2001 c.457 §1; 2003 c.576 §543; 2005 c.726 §11; 2011 c.597 §142; 2013 c.514 §7]

689.139 State Board of Pharmacy Account; disposition of receipts. The State Board of Pharmacy Account is established in the State Treasury, separate and distinct from the General Fund. All moneys received by the State Board of Pharmacy shall be deposited into the account and are continuously appropriated to the board to carry out the duties, functions and powers of the board. Any interest or other income from moneys in the account shall be credited to the account. [2005 c.726 §10]

689.140 [Amended by 1963 c.586 §3; repealed by 1969 c.514 §57]

689.145 Enforcement powers of board. The responsibility for enforcement of the provisions of this chapter is vested in the State Board of Pharmacy. The board shall have all of the duties, powers and authority specifically granted by and necessary and proper to the enforcement of this chapter, as well as such other duties, powers and authority as it may be granted from time to time by law. [1979 c.777 §6; 1985 c.565 §99]

689.150 [Amended by 1969 c.514 §46; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.151 Board control over licensing, standards and discipline. The State Board of Pharmacy shall be responsible for the control and regulation of the practice of pharmacy in this state including, but not limited to, the following:

(1) The licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy under the provisions of this chapter;

(2) The renewal of licenses to engage in the practice of pharmacy;

(3) The determination and issuance of standards based on nationally recognized standards of practice and accreditation criteria for recognition and approval of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, and the specification and enforcement of requirements for practical training, including internship;

(4) The enforcement of those provisions of this chapter relating to the conduct or competence of pharmacists practicing in this state, and the suspension, revocation or restriction of licenses to engage in the practice of pharmacy;

(5) The training, qualifications and employment of pharmacy interns; and

(6) The licensing of pharmacy technicians. [Formerly 689.245; 2001 c.595 §1; 2005 c.313 §10]

689.153 Continuing authority of board upon lapse, suspension, revocation or voluntary surrender of license or certificate. The lapse, suspension or revocation of a license or certificate of registration by the operation of law or by order of the State Board of Pharmacy or by the decision of a court of law, or the voluntary surrender of a license by a licensee or of a certificate of registration by the holder of the certificate, does not deprive the board of jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee or certificate holder or revise or render null and void an order of disciplinary action against the licensee or certificate holder. [2007 c.90 §4]

689.155 Authority of board over medications, drugs, devices and other materials; rules. The State Board of Pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

(1) The regulation of the sale at retail, the administering by pharmacists to the extent provided in ORS 689.645 and 689.655 and the dispensing of medications, drugs, devices and other materials including the right to seize any such drugs, devices and other materials found to be detrimental to the public health and welfare by the board after appropriate hearing as required under ORS chapter 183.

(2) The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding, administering and dispensing of such medications, drugs, devices and other materials within the practice of pharmacy and any drug outlet.

(3) The control of the purity and quality of such medications, drugs, devices and other materials within the practice of pharmacy and any drug outlet.

(4) The issuance and renewal of certificates of registration of drug outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs, receiving and collecting annual fees therefrom and suspending, revoking or refusing to renew such registration in the manner provided in this chapter.

(5) In conjunction with the regularly constituted law enforcement agencies of this state, enforce all laws of the state which pertain to the practice of pharmacy, the manufacture, production, sale or distribution of drugs, chemicals and poisons, and to their standard of strength and purity.

(6) Investigate all complaints of alleged violations of this chapter and take necessary action as the board may require or direct.

(7) Pursuant to ORS chapter 183, make such rules as are necessary and feasible for carrying out ORS 453.175, 453.185, 475.005, 475.135 and 475.185 and this chapter and make rules relating to controlled substances, designated as such pursuant to ORS 475.025 and 475.035.

(8) At all reasonable hours, in performance of the duties imposed by this section, enter, or cause its authorized representatives to enter upon, and examine the premises or records required by law of any drug outlet under the jurisdiction of the board.

(9) Assist the regularly constituted law enforcement agencies of this state in enforcing ORS 453.005 to 453.135, 475.005 and 475.135 and this chapter by prosecution in the courts of this state or otherwise.

(10) Cause to have made a regular inspection of all pharmacies.

(11) Pursuant to ORS chapter 183, make such rules as are necessary for pharmacies, drug manufacturers and wholesalers to sell or otherwise lawfully distribute designated pharmaceutical agents to licensed optometrists consistent with the provisions of ORS 683.010 to 683.340. [1979 c.777 §19; 1985 c.565 §100; 1999 c.350 §4; 2001 c.632 §5]

689.160 [Amended by 1969 c.514 §4; 1979 c.785 §8; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.165 Officers; executive director. (1) The State Board of Pharmacy shall elect from its members a president and vice president and such other officers as it deems appropriate and necessary to the conduct of its business. The President of the State Board of Pharmacy shall preside at all meetings of the board and shall be responsible for the performance of all of the duties and functions of the board required or permitted by this chapter. If the president is absent or unable to preside, the vice president shall preside. Each additional officer elected by the board

shall perform those duties normally associated with their position and such other duties assigned from time to time by the board.

(2) Officers elected by the board shall serve terms of one year commencing with the day of their election, and ending upon election of their successors and shall serve no more than one consecutive full term in each office to which they are elected.

(3) The executive director of the board shall be responsible for the performance of the regular administrative functions of the board and such other duties as the board may direct. The executive director shall not perform any discretionary or decision-making functions for which the board is solely responsible. [1979 c.777 §13; 1985 c.565 §101; 2009 c.756 §75]

689.170 [Amended by 1963 c.586 §4; 1969 c.514 §5; 1973 c.743 §2; 1979 c.514 §1; 1979 c.744 §61; 1979 c.785 §9; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.175 Compensation of board members and executive director. (1) Each member of the State Board of Pharmacy shall receive compensation for each day on which the member is engaged in performance of the official duties of the board, and reimbursement for all expenses incurred in connection with the discharge of such official duties as provided in ORS 292.495.

(2) The Executive Director of the State Board of Pharmacy shall receive, as compensation, an annual salary payable monthly, the amount of which shall be determined by the board, and reimbursement for all expenses incurred in connection with performance of official duties, subject to applicable law and to the rules of the Oregon Department of Administrative Services. [1979 c.777 §14]

689.180 [Amended by 1969 c.514 §3; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.185 Meetings. (1) The State Board of Pharmacy shall meet at least once every three months to transact its business. One such meeting held during each fiscal year of the state shall be designated by rule as the annual meeting and shall be for the purpose of electing officers and for the reorganization of the board. The board shall meet at such additional times as it may determine. Such additional meetings may be called by the president of the board or by majority of members of the board.

(2) The board shall meet at such place as it may from time to time determine. The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate subsequent notice.

(3) Notice of all meetings of the board shall be given in the manner and pursuant to requirements prescribed by the state's applicable rules.

(4) A majority of the members of the board shall constitute a quorum for the conduct of a board meeting and, except where a greater number is required by ORS 167.203, 414.325, 430.405, 435.010, 453.025, 475.005, 475.135, 475.185, 475.752, 475.906 and 616.855 and this chapter, or by any rule of the board, all actions of the board shall be by a majority of a quorum.

(5) All board meetings and hearings shall be open to the public. The board may, in its discretion and according to law, conduct any portion of its meeting in executive session closed to the public. [1979 c.777 §15; 1999 c.605 §7; 1999 c.1051 §138]

689.195 Employees. (1) The State Board of Pharmacy may, in its discretion, employ persons in positions or capacities as it deems necessary to the proper conduct of board business and to the fulfillment of the board's responsibilities as defined by this chapter.

(2) The employees of the board other than the executive director shall receive, as compensation, an annual salary payable monthly, the amount of which shall be determined by

law, and reimbursement for expenses incurred in connection with performance of their official duties. [1979 c.777 §16; 1985 c.565 §102; 2009 c.756 §76]

689.205 Rules. The State Board of Pharmacy shall make, adopt, amend and repeal such rules as may be deemed necessary by the board, from time to time, for the proper administration and enforcement of this chapter. Such rules shall be adopted in accordance with the procedures specified in ORS chapter 183. [1979 c.777 §17; 1985 c.565 §103]

689.207 Authority of board to require fingerprints. For the purpose of requesting a state or nationwide criminal records check under ORS 181A.195, the State Board of Pharmacy may require the fingerprints of a person who is:

(1) Applying for a license or certificate that is issued by the board;

(2) Applying for renewal of a license or certificate that is issued by the board; or

(3) Under investigation by the board. [2005 c.730 §68]

Note: 689.207 was enacted into law by the Legislative Assembly but was not added to or made a part of ORS chapter 689 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

689.210 [Amended by 1961 c.216 §1; 1965 c.580 §5; 1967 c.287 §1; 1969 c.514 §6; 1973 c.743 §3a; 1973 c.827 §75; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.215 [1965 c.580 §3; repealed by 1967 c.287 §3]

689.220 [Repealed by 1969 c.514 §57]

PRACTICE OF PHARMACY

689.225 License requirement; exceptions; possession of drugs; regulation of pharmacy technicians; rules; penalty. (1) A person may not engage in the practice of pharmacy unless the person is licensed under this chapter. Nothing in this section prevents physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

(2) A person may not take, use or exhibit the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import unless the person is licensed to practice pharmacy under this chapter.

(3) A pharmacist may not possess personally or store drugs other than in a licensed pharmacy except for those drugs legally prescribed for the personal use of the pharmacist or when the pharmacist possesses or stores the drugs in the usual course of business and within the pharmacist's scope of practice. An employee, agent or owner of any registered manufacturer, wholesaler or pharmacy may lawfully possess legend drugs if the person is acting in the usual course of the business or employment of the person.

(4) The State Board of Pharmacy shall adopt rules relating to the use of pharmacy technicians working under the supervision, direction and control of a pharmacist. For retail and institutional drug outlets, the board shall adopt rules which include requirements for training, including provisions for appropriate on-the-job training, guidelines for adequate supervision, standards and appropriate ratios for the use of pharmacy technicians. Improper use of pharmacy technicians is subject to the reporting requirements of ORS 689.455.

(5) The mixing of intravenous admixtures by pharmacy technicians working under the supervision, direction and control of a pharmacist is authorized and does not constitute the practice of pharmacy by the pharmacy technicians.

(6) Any person who is found to have unlawfully engaged in the practice of pharmacy is guilty of a Class A misdemeanor. [1979 c.777 §21; 1983 c.402 §3; 1985 c.565 §104; 1989 c.608 §2; 1997 c.729 §2; 2001 c.278 §1; 2009 c.326 §3]

689.230 [Amended by 1967 c.287 §2; 1969 c.514 §7; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.235 [1969 c.514 §8; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.240 [Amended by 1963 c.96 §3; 1967 c.183 §2; 1969 c.514 §9; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.245 [1979 c.777 §18; 1985 c.565 §105; renumbered 689.151 in 1997]

689.250 [Amended by 1955 c.132 §1; 1963 c.96 §4; 1965 c.580 §6; 1967 c.183 §3; 1969 c.514 §10; 1973 c.612 §24; 1975 c.686 §9; repealed by 1979 c.777 §59]

689.255 Qualifications for licensure by examination. (1) To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:

(a) Have submitted a written application in the form prescribed by the State Board of Pharmacy.

(b) Have attained the age of 18 years.

(c) Be of good moral character and temperate habits.

(d) Have completed requirements for the first professional undergraduate degree as certified by a school or college of pharmacy which has been approved by the board.

(e) Have completed an internship or other program which has been approved by the board, or demonstrated to the board's satisfaction experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the board.

(f) Have successfully passed an examination approved by the board.

(g) Have paid the fees specified by the board for examination and issuance of license.

(2)(a) The board shall approve the content and subject matter of each examination and determine which persons have successfully passed the examination.

(b) The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ and cooperate with any organization or consultant in the preparation and grading of an appropriate examination, but shall retain the sole discretion and responsibility of determining which applicants have successfully passed such an examination.

(3)(a) All applicants for licensure by examination shall obtain professional and practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the board shall determine.

(b) The board shall establish standards for internship or any other program necessary to qualify an applicant for the licensure examination based on nationally recognized standards of practice and shall also determine the necessary qualifications of any preceptors used in any internship or other program.

(4) Any person who has received a professional degree from a school or college of pharmacy located outside the United States which has not been approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in the State of Oregon may be

deemed to have satisfied the degree requirements of subsection (1)(d) of this section by verification to the board of the academic record and graduation of the person and by meeting such other requirements as the board may establish. The board may require such person to successfully pass an examination or examinations given or approved by the board to establish proficiency in English and equivalency of education of such person with qualified graduates of a degree program referred to in subsection (1)(d) of this section as a prerequisite of taking the licensure examination provided for in subsection (1)(f) of this section.

(5) An applicant meets the requirements of subsection (1)(e) or (3) of this section if the applicant provides the board with documentation of military experience that the board determines is substantially equivalent to the experience required by subsection (1)(e) or (3) of this section. [1979 c.777 §22; 1987 c.108 §4; 1999 c.59 §205; 2009 c.756 §77; 2012 c.43 §22]

689.260 [Amended by 1969 c.514 §12; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.265 Qualifications for licensure by reciprocity. (1) To obtain a license as a pharmacist by reciprocity, an applicant for licensure shall:

(a) Have submitted a written application in the form prescribed by the State Board of Pharmacy.

(b) Have attained the age of 18 years.

(c) Have good moral character and temperate habits.

(d) Have possessed at the time of initial licensure as a pharmacist such other qualifications necessary to have been eligible for licensure at that time in this state.

(e) Have engaged in the practice of pharmacy for a period of at least one year or have met the internship requirements of this state within the one-year period immediately previous to the date of such application.

(f) Have presented to the board proof of initial licensure by examination and proof that such license and any other license or licenses granted to the applicant by any other state or states have not been suspended, revoked, canceled or otherwise restricted for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy.

(g) Have successfully passed an examination in jurisprudence approved by the board.

(h) Have paid the fees specified by the board for issuance of a license.

(i) Have submitted to the board proof of a professional degree that meets the requirements of ORS 689.255 (4), if the applicant has received a professional degree from a school or college of pharmacy located outside the United States.

(2) No applicant shall be eligible for licensure by reciprocity unless the state in which the applicant was initially licensed as a pharmacist also grants reciprocal licensure to pharmacists duly licensed by examination in this state, under like circumstances and conditions. [1979 c.777 §23; 2001 c.585 §1; 2009 c.756 §78]

689.270 [Amended by 1963 c.586 §5; 1969 c.514 §14; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.275 Renewal of licenses; rules; fees. (1) Each pharmacist shall apply for renewal of license annually no later than June 30 or no later than such date as may be specified by rule of the State Board of Pharmacy. The board shall renew the license of each pharmacist who is qualified to engage in the practice of pharmacy.

(2) The board shall specify by rule the procedures to be followed, in addition to those specified by ORS 689.285, and the fees to be paid for renewal of licenses.

(3)(a) All pharmacists in good standing who have been licensed pharmacists for at least 20 years and who are retired from practice of pharmacy are exempt from further payment of license fees until they again engage in the practice of pharmacy. No retired pharmacist shall engage in the practice of pharmacy without first paying all fees for the year in which the pharmacist resumes practice and producing evidence satisfactory to the board of continued professional competence.

(b) Failure to comply with the requirements of paragraph (a) of this subsection shall be considered the practice of pharmacy without a license. [1979 c.777 §24; 2007 c.768 §51]

689.280 [1965 c.580 §2; 1967 c.183 §4; 1969 c.514 §13; 1973 c.743 §4; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.285 Continuing pharmacy education; rules; fees. (1) The Legislative Assembly finds and declares that:

(a) The continuous introduction of new medical agents and the changing concepts of the delivery of health care services in the practice of pharmacy make it essential that a pharmacist undertake a continuing education program in order to maintain professional competency and improve professional skills;

(b) The state has a basic obligation to regulate and control the profession of pharmacy in order to protect the public health and welfare of its citizens; and

(c) It is the purpose of this chapter to protect the health and welfare of Oregon citizens and to ensure uniform qualifications and continued competency of licensed pharmacists by requiring participation in a continuing pharmacy education program as a condition for renewal of licenses to practice pharmacy.

(2) All pharmacists licensed in the State of Oregon on and after October 3, 1979, shall satisfactorily complete courses of study and satisfactorily continue their education by other means as determined by the State Board of Pharmacy in subjects relating to the practice of the profession of pharmacy in order to be eligible for renewal of licenses.

(3) In accordance with applicable provisions of ORS chapter 183, the board shall adopt reasonable rules:

(a) Prescribing the procedure and criteria for approval of continuing pharmacy education programs, including the number of hours of courses of study necessary to constitute a continuing pharmacy education unit and the number of continuing pharmacy education units required annually for renewal of a pharmacist license.

(b) Prescribing the scope of the examinations given by the board including grading procedures.

(c) Prescribing the content of the form to be submitted to the board certifying completion of an approved continuing pharmacy education program.

(d) Necessary to carry out the provisions of this chapter.

(e) Prescribing the completion of:

(A) A pain management education program approved by the board and developed in conjunction with the Pain Management Commission established under ORS 413.570; or

(B) An equivalent pain management education program, as determined by the board.

(4) In adopting rules pursuant to subsection (3) of this section, the board shall consider:

(a) The need for formal regularly scheduled pharmacy education programs.

(b) Alternate methods of study including home-study courses, seminars or other such programs for those persons who, upon written application to the board and for good cause shown, demonstrate their inability to attend regularly scheduled formal classroom programs.

(c) The necessity for examinations or other evaluation methods used to ensure satisfactory completion of the continuing pharmacy education program.

(5) The board may contract for the providing of educational programs to fulfill the requirements of this chapter. The board is further authorized to treat funds set aside for the purpose of continuing education as state funds for the purpose of accepting any funds made available under federal law on a matching basis for the promulgation and maintenance of programs of continuing education. In no instance shall the board require a greater number of hours of study than it provides or approves in the State of Oregon and which are available on the same basis to all licensed pharmacists.

(6) The board may levy an additional fee, established by the board by rule, for each license renewal to carry out the provisions of this chapter. [1979 c.777 §26; 1983 c.402 §5; 1985 c.565 §106; 1993 c.571 §6; 1993 c.742 §55; 2001 c.281 §1; 2005 c.162 §3; 2013 c.514 §8]

689.290 [1969 c.514 §56; 1971 c.92 §2; 1973 c.743 §5; 1977 c.745 §43; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.295 Practice of clinical pharmacy. In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may engage in the practice of clinical pharmacy. [2015 c.362 §2]

REGULATION OF DRUG OUTLETS

689.305 Registration of drug outlets; rules. (1) All drug outlets shall annually register with the State Board of Pharmacy.

(2)(a) Each drug outlet shall apply for a certificate of registration in one or more of the following classifications:

(A) Retail drug outlet.

(B) Institutional drug outlet.

(C) Manufacturing drug outlet.

(D) Wholesale drug outlet.

(E) Nonprescription drug outlet.

(b) No individual who is employed by a corporation which is registered under any classification listed in paragraph (a) of this subsection need register under the provisions of this section.

(3) The board shall establish by rule under the powers granted to it under ORS 689.155 and 689.205 the criteria which each drug outlet must meet to qualify for registration in each classification designated in subsection (2)(a) of this section. The board may issue various types of certificates of registration with varying restrictions to the designated outlets where the board deems it necessary by reason of the type of drug outlet requesting a certificate.

(4) It shall be lawful for a drug outlet registered under this section to sell and distribute nonprescription drugs. Drug outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. [1979 c.777 §30; 1993 c.571 §8]

689.310 [Amended by 1953 c.126 §2; 1963 c.96 §5; 1967 c.183 §5; 1969 c.514 §15; 1979 c.336 §2; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.315 Application; rules. (1) The State Board of Pharmacy shall specify by rule the registration procedures to be followed, including but not limited to specification of forms for use

in applying for such certificates of registration and times, places and fees for filing such application.

(2) Applications for certificates of registration shall include the following information about the proposed drug outlet:

(a) Ownership;

(b) Location;

(c) Identity of pharmacist licensed to practice in the state, who shall be the pharmacist in charge of the drug outlet, where one is required by this chapter, and such further information as the board may deem necessary; and

(d) The identity of any person who has incident of ownership in a pharmacy who also has a financial interest in any long term care facility, as defined in ORS 442.015.

(3) Manufacturers and wholesalers shall keep all records and files of their transactions for a period of three years from the date of the inception of such records and files.

(4)(a) Manufacturers and wholesalers shall acquire a separate registration for each place at which they carry on their business as a manufacturer or wholesaler within this state.

(b) Certificates of registration issued by the board pursuant to this chapter shall not be transferable or assignable and shall be conspicuously displayed at each registered place of business.

(5) The board shall specify by rule minimum standards for the professional responsibility in the conduct of any drug outlet that has employees or personnel engaged in the practice of pharmacy. The board is specifically authorized to require that the portion of the facility to which such certificate of registration applies be operated only under the direct supervision of no less than one pharmacist licensed to practice in this state and not otherwise, and to provide such other special requirements as deemed necessary. [1979 c.777 §31a; 1985 c.565 §107; 1993 c.571 §9]

689.320 [Amended by 1963 c.586 §6; 1965 c.157 §1; 1967 c.261 §1; 1969 c.514 §16; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.325 Required reports. (1) All registered drug outlets shall report to the State Board of Pharmacy the occurrence of any of the following changes within the times specified by the board by rule:

(a) Permanent closing;

(b) Change of ownership, management, location or pharmacist in charge; or

(c) Any and all other matters and occurrences as the board may require by rule.

(2) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the board. [1979 c.777 §32; 1993 c.571 §10]

689.330 [Amended by 1955 c.94 §1; 1957 c.598 §1; 1963 c.96 §6; 1969 c.514 §18; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.335 Certificate required; reinstatement. (1) No drug outlet designated in ORS 689.305 shall be operated until a certificate of registration has been issued to said facility by the State Board of Pharmacy. Upon the finding of a violation of ORS 689.305 or 689.405, the board may impose one or more of the penalties under ORS 689.445.

(2) Reinstatement of a certificate that has been suspended, revoked or restricted by the board may be granted in accordance with the procedures specified by ORS 689.445 (2). [1979 c.777 §33; 1981 c.277 §3]

689.340 [Amended by 1969 c.514 §19; 1973 c.612 §25; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.342 [1989 c.667 §1; 2005 c.313 §1; 2007 c.70 §313; repealed by 2009 c.697 §14]

689.344 [1989 c.667 §2; 2005 c.313 §2; 2007 c.70 §314; repealed by 2009 c.697 §14]

689.346 [1989 c.667 §3; 2007 c.70 §315; repealed by 2009 c.697 §14]

689.348 [1989 c.667 §4; 2005 c.313 §3; repealed by 2009 c.697 §14]

689.350 [Amended by 1965 c.356 §1; 1967 c.183 §6; 1969 c.514 §20; repealed by 1977 c.842 §2 and 1979 c.777 §59]

689.352 [1989 c.667 §5; 2005 c.313 §4; repealed by 2009 c.697 §14]

689.354 [1989 c.667 §6; 2005 c.313 §5; repealed by 2009 c.697 §14]

689.356 [1989 c.667 §7; 1991 c.703 §32; 2005 c.313 §6; repealed by 2009 c.697 §14]

689.360 [1965 c.580 §8; 1969 c.514 §17; repealed by 1977 c.842 §45 and 1979 c.777 §59]

DISCIPLINE

689.405 Grounds for discipline; investigation; procedure as contested case. (1) The State Board of Pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the license of any person or the certificate of registration of any drug outlet upon one or more of the following grounds:

(a) Unprofessional conduct as that term is defined by the rules of the board.

(b) Repeated or gross negligence.

(c) Incapacity of a nature that prevents a person from engaging in the activity for which the person is licensed with reasonable skill, competence and safety to the public.

(d) Impairment as defined in ORS 676.303.

(e) Being found guilty by the board of a violation of subparagraph (B) of this paragraph, or by a court of competent jurisdiction of one or more of the following:

(A) A felony, as defined by the laws of this state; or

(B) Violations 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) Fraud or intentional misrepresentation by a licensee or registrant in securing or attempting to secure the issuance or renewal of a license.

(g) Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a license, or falsely using the title of pharmacist.

(h) Aiding and abetting an individual in performing the duties of a pharmacy technician without licensing.

(i) 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, 475.744, 475.752 to 475.980 or this chapter or rules adopted pursuant to ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.744, 475.752 to 475.980 and this chapter.

(j) Disciplinary action by another state regarding a license, based upon acts by the licensee similar to acts described in this subsection. A certified copy of the record of disciplinary action of the state taking the disciplinary action is conclusive evidence thereof.

(2) Upon receipt of a complaint under this chapter, the board shall conduct an investigation as described under ORS 676.165.

(3) Actions taken under subsection (1) of this section shall be considered a contested case under ORS chapter 183. [1979 c.777 §§27,28; 1981 c.277 §4; 1985 c.131 §4; 1987 c.736 §1; 1995 c.440 §11; 1997 c.729 §3; 1997 c.791 §48; 2005 c.313 §12; 2009 c.756 §79]

689.410 [Amended by 1963 c.586 §7; 1965 c.580 §7; 1969 c.514 §25; 1977 c.745 §44; repealed by 1979 c.777 §59]

689.413 [1969 c.514 §26; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.415 [1969 c.514 §27; repealed by 1977 c.842 §45 and 1979 c.777 §59]
689.420 [Repealed by 1969 c.514 §57]

689.423 [1971 c.734 §143; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.425 [1969 c.514 §30; repealed by 1971 c.734 §21]

689.430 [Amended by 1969 c.514 §29; repealed by 1971 c.734 §21]

689.435 [1971 c.734 §144; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.440 [Repealed by 1969 c.514 §57]

689.445 Penalties and reinstatement. (1) Upon the finding of the existence of grounds for discipline of any person holding a license, seeking a license or renewal of a license under the provisions of ORS 435.010 to 435.030, 475.125 and 475.135 and this chapter, the State Board of Pharmacy may impose one or more of the following penalties:

(a) Suspension of the offender's license for a term to be determined by the board;

(b) Revocation of the offender's license;

(c) Restriction of the offender's license to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the board;

(d) A civil penalty not to exceed:

(A) $1,000 for each offense committed by an individual; and

(B) $10,000 for each offense committed by a drug outlet;

(e) Refusal to renew offender's license; or

(f) Placement of the offender on probation and supervision by the board for a period to be determined by the board.

(2) Any person whose license issued pursuant to this chapter has been suspended, revoked or restricted pursuant to this chapter, whether voluntarily or by action of the board, shall have the right, at reasonable intervals, to petition the board for reinstatement of such license. Such petition shall be made in writing and in the form prescribed by the board. Upon investigation and hearing, the board may in its discretion grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such

modifications. Pardon and restoration of civil rights to any person formerly licensed by the board does not obligate the board to restore revoked, restricted or suspended licenses.

(3) Nothing in this chapter shall be construed as barring criminal prosecutions for violations of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.744, 475.752 to 475.980 and this chapter where such violations are deemed as criminal offenses in other statutes of this state or of the United States.

(4) Civil penalties under this section shall be imposed as provided in ORS 183.745.

(5) All penalties recovered under ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.744, 475.752 to 475.980 and this chapter shall be deposited into the State Board of Pharmacy Account established in ORS 689.139. [1979 c.777 §29; 1985 c.131 §5; 1991 c.734 §75; 1995 c.440 §12; 1997 c.729 §4; 2005 c.726 §12; 2007 c.90 §1]

689.450 [Amended by 1969 c.514 §47; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.455 Duty to report suspected violations and prohibited conduct; liability for reporting; confidentiality of report. (1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a pharmacist or pharmacy technician shall report:

(a) Any suspected violations of this chapter or of ORS 475.005 to 475.285 and 475.752 to 475.980 to the State Board of Pharmacy; and

(b) Any prohibited conduct as defined in ORS 676.150 in the manner provided in ORS 676.150.

(2) Any pharmacist or pharmacy technician who reports to the board as required by subsection (1) of this section in good faith shall not be subject to an action for civil damages as a result thereof.

(3) Any information that the board obtains pursuant to ORS 689.405 or 689.445 or this section is confidential as provided under ORS 676.175. [1985 c.131 §3; 1995 c.440 §40; 1997 c.791 §49; 2001 c.595 §4; 2009 c.536 §18]

689.460 [1973 c.743 §11; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.475 [1967 c.636 §2; 1969 c.514 §32; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.480 [1967 c.636 §3; 1969 c.514 §33; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.485 [1967 c.636 §4; 1969 c.514 §34; repealed by 1977 c.842 §45 and 1979 c.777 §59]

PHARMACY TECHNICIANS

689.486 When license required; qualifications for licensure; renewal; supervision required. (1) It shall be unlawful for any person to perform the duties of a pharmacy technician or use the title of pharmacy technician unless licensed to do so under the provisions of this chapter.

(2) To be licensed to perform the duties of a pharmacy technician, a person shall:

(a) Submit a license application in the manner prescribed by the State Board of Pharmacy; and

(b) Pay the license fee established by the board.

(3) The license application prescribed by the board shall include, but not be limited to:

(a) The name and address of the applicant;

(b) The educational qualifications of the applicant;

(c) The work history of the applicant; and

(d) The applicant's criminal offender record of any conviction or of any arrest less than one year old on which there has been no acquittal or dismissal.

(4) A license under this section expires annually. To renew a license to perform the duties of a pharmacy technician, a person shall:

(a) Submit the application for renewal of a license in the form prescribed by the board;

(b) Pay the license renewal fee established by the board;

(c) Pay the fee for late license renewal, if applicable;

(d) Provide updated information regarding educational qualifications, work history and criminal arrest and conviction history; and

(e) Comply with all other requirements for license renewal established by the board.

(5) No person may employ an individual to perform the duties of a pharmacy technician unless the individual is licensed to perform the duties of a pharmacy technician under this chapter.

(6) A person licensed to perform the duties of a pharmacy technician may perform the duties of a pharmacy technician only under the supervision, direction and control of a licensed pharmacist. [1997 c.729 §6; 2001 c.595 §2; 2005 c.313 §7; 2013 c.514 §9]

689.490 Board to establish licensing system; rules; fees. (1) In accordance with any applicable provisions of ORS chapter 183, the State Board of Pharmacy, by rule, shall establish a licensing system for persons who perform the duties of a pharmacy technician. The licensing system shall include but not be limited to the following provisions:

(a) Prescribing the form and content of and the procedures for submitting an application for the issuance or renewal of a technician license.

(b) Prescribing the fee for a license, for renewal of a license and for late renewal of a license.

(c) Allowing an applicant to meet educational and experience requirements by providing the board with documentation of military training or experience that is substantially equivalent to the education or experience required by the board.

(2) The board may refuse to issue or renew, or may suspend, revoke or restrict a technician license:

(a) For any reason listed under ORS 689.405 (1);

(b) If the applicant is not authorized to work for hire under Oregon law; or

(c) For any other grounds that the board, in its discretion, believes would disqualify the applicant for a license.

(3) Denial of a license under subsection (2) of this section is a contested case under ORS chapter 183. [1997 c.729 §7; 2001 c.595 §3; 2005 c.313 §8; 2012 c.43 §23; 2013 c.514 §10]

689.495 Provision of licensing information. (1) Upon the written request of a pharmacist, the State Board of Pharmacy shall provide the name, address, educational qualifications, work history, technician license history and criminal arrest and conviction history of any pharmacy technician licensed with the board. Information provided by the board pursuant to a request under this section shall be in writing and may be provided to the requester by means of facsimile or other electronic transmission or the United States Postal Service.

(2) For purposes of this section:

(a) "Written request" includes but is not limited to a request received by means of facsimile or other electronic transmission.

(b) "Work history" includes but is not limited to information reported to the board pursuant to ORS 689.497 to the extent the information is not exempt from disclosure under ORS 676.175. [1997 c.729 §8; 2001 c.595 §5; 2005 c.313 §9]

689.497 Report required upon termination of pharmacy technician. (1) A pharmacy that terminates a pharmacy technician shall report the termination to the State Board of Pharmacy. In the sole discretion of the pharmacy, the pharmacy may report the reason for the termination.

(2) A pharmacy reporting the termination of a pharmacy technician under subsection (1) of this section shall provide the pharmacy technician an opportunity to issue a statement accompanying the report of termination. The statement of the pharmacy technician may include any mitigating factors or other information the pharmacy technician deems relevant to the termination.

(3) A pharmacy, pharmacist, pharmacy technician or any other person who, in good faith, submits a report of termination of a pharmacy technician under the provisions of this section is not liable for any civil damages as a result of submitting the report.

(4) The information provided to the board pursuant to this section is:

(a) Subject to disclosure as provided in ORS 689.495; and

(b) Admissible as evidence for any purpose in any civil proceeding before a court, agency, board or third-party dispute resolution tribunal.

(5) Nothing in subsection (3) of this section shall affect the admissibility in evidence of the records of a pharmacy or pharmacist that pertain to the work history or termination of employment of a pharmacy technician. [2001 c.595 §7]

689.499 Pharmacy technician specialized education program; rules. (1)(a) The State Board of Pharmacy may by rule identify activities performed by a pharmacy technician for which a specialized education program may be required.

(b) If the board identifies an activity requiring specialized education under this subsection, the board shall approve no fewer than two specialized education programs to provide the specialized education.

(c) Upon receipt of evidence satisfactory to the board that a pharmacy technician has satisfactorily completed a specialized education program approved by the board, the board shall note the specialized education on the license of the pharmacy technician.

(2) The board may establish standards for renewal or revocation of a notation of specialized education under this section.

(3) As used in this section, "specialized education program" means:

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

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

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

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

(C) A trade association recognized by the board as representing pharmacies. [2005 c.313 §16]

REQUIREMENTS RELATING TO SALES

689.505 Labeling requirements; rules. (1)(a) Except as specifically provided by law, no person shall distribute or dispense any drug without affixing to the authorized container a clear and legible label, either printed or written, bearing the name of the drug and the name and place of

business of the person distributing or dispensing the drug, and any other information required by state law or rules or federal law or regulations under whose supervision the drug is delivered or dispensed.

(b) Labeling requirements regarding any drug may be changed or exemption therefrom granted by the State Board of Pharmacy in the form of a special permit if the board determines that a change or exemption is in the best interest of public health and safety.

(2)(a) No manufacturer or wholesaler subject to ORS 689.305 shall sell or otherwise distribute, or offer to sell or otherwise distribute, any drug for use in a:

(A) Parcel, package or container not bearing a label specifying the name, active ingredients or contents, quality and quantity of the drug.

(B) Misbranded parcel, package or container.

(b) A parcel, package or container is misbranded:

(A) If its labeling is false or misleading in any particular.

(B) Unless it bears a label containing the name and business address of the manufacturer, packer, distributor or wholesaler, and an accurate statement of the quantity of the drug in terms of weight, measure or numerical count, exclusive of wrappers, cartons, containers or other materials packed with such drug.

(C) In case it contains controlled substances which the board finds and by rule designates after reasonable notice and opportunity for hearing to be habit forming, unless it bears the statement “Warning--May Be Habit Forming.”

(D) Unless it bears a label with adequate directions for the safe use of the drug for specified conditions, and adequate warning against use in those pathological conditions or by children where such use may be dangerous to the health or welfare of a user.

(E) Unless it bears a label with true representations of the intended uses of the drug and no false claims or representations are made of the drug in accompanying literature or advertising.

(3) This section does not apply to parcels, packages or containers containing:

(a) Drugs prepared and packaged solely for use by a pharmacist in compounding prescriptions or for dispensing in dosage unit form upon a prescription, except that such parcels, packages or containers must bear the name and business address of the manufacturer and, if different, the name and business address of the distributor of the drug, and the legend “Caution: Federal Law Prohibits Dispensing Without Prescription” or an equivalent legend.

(b) Drugs intended solely for use in the professional diagnosis of disease, except that such parcels, packages or containers shall bear the statement “Diagnostic Reagent--For Professional Use Only.”

(c) Coloring agents, emulsifiers, excipients, flavorings, lubricants, preservatives and other like inactive ingredients used in the manufacture of drugs.

(4) The board shall by rule exempt from any labeling or packaging requirement of this section drugs which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed. However, such drugs must not be adulterated or misbranded upon removal from such processing, labeling or repacking establishment.

(5) A pharmacist or pharmacy intern shall not dispense, on the prescription of a practitioner, any drug without affixing to the container thereof a clear and legible label. The label may be printed or written. Except as provided in subsection (6) of this section, the pharmacist or pharmacy intern shall state or cause to be stated on the label the following:

(a) The name of the drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed along with the name of the drug distributor or manufacturer, its quantity per unit and the directions for its use stated in the prescription. However, if the drug is a compound, the quantity per unit need not be stated.

(b) The name of the practitioner prescribing the drug.

(c) The name and place of business of the pharmacist or the name and place of business of the pharmacy for which the pharmacist or pharmacy intern is acting.

(d) The name of the patient, unless the drug is prescribed to a partner of a patient as defined in ORS 676.350 in accordance with rules adopted under ORS 676.350 authorizing the practice of expedited partner therapy.

(e) When applicable and as determined by the State Board of Pharmacy, an expiration date after which the patient should not use the drug.

(6) If the prescribing practitioner so directs, the prescription label shall not state the name and quantity per unit of the drug.

(7) The State Board of Pharmacy shall determine those drugs which must bear an expiration date under subsection (5)(e) of this section.

(8) As used in this section, "compound" means a drug containing two or more medically active ingredients.

(9) No person shall deliver or dispense any drug for use by the ultimate consumer without labeling the drug container as required in this section.

(10) In addition to the labeling requirements imposed by subsections (1) to (9) of this section, the board may impose by rule requirements for drug code imprints on solid dose legend drugs. [1979 c.777 §34a; 1993 c.571 §13; 2009 c.522 §2]

689.508 Prescription records. The original record of every prescription filled by a pharmacy must be kept on file for three years at the pharmacy or as specified by State Board of Pharmacy rule. The prescription record must contain the date of the transaction and the brand name, or if the drug has no brand name, the generic name and the name of the manufacturer of any drug substituted pursuant to ORS 689.515. If the prescription may be communicated to the pharmacy by oral or electronic means, the prescription information may be recorded and stored in an electronic form that allows for ready retrieval. Prescriptions maintained in the file required under this section must be readily accessible to the board for inspection. [2003 c.103 §2; 2009 c.756 §80]

689.510 [Amended by 1953 c.433 §1; 1971 c.650 §39; 1973 c.792 §44; 1977 c.688 §1; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.515 Regulation of generic drugs; substitutions; rules. (1) As used in this section unless the context requires otherwise:

(a) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging.

(b) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including but not limited to tablets, capsules, oral solutions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

(c) "Generic name" means the official title of a drug or drug ingredients published in the latest edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

(d) "Substitute" means to dispense without the prescriber's express authorization a different drug product in place of the drug ordered or prescribed.

(e) "Therapeutically equivalent" means drugs that are approved by the United States Food and Drug Administration for interstate distribution and the Food and Drug Administration has determined that the drugs will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

(2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs otherwise, a pharmacist may substitute as follows:

(a) A drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent.

(b) When the prescriber is not reasonably available for consultation and the prescribed drug does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the prescribed drug so long as the form dispensed or administered has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed.

(3) A practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(4) A pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on the sign must be in block letters not less than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

(5) A pharmacist may substitute a drug product under this section only when there will be a savings in or no increase in cost to the purchaser.

(6) If the practitioner prescribes a drug by its generic name, the pharmacist shall, consistent with reasonable professional judgment, dispense or administer the lowest retail cost, effective brand which is in stock.

(7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substituted drug as authorized by subsection (2) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, the pharmacist shall label the prescription container with the generic name of the drug dispensed along with the name of the drug manufacturer.

(8) A prescription dispensed by a pharmacist must bear upon the label the name of the medication in the container or shall be labeled as intended by the prescriber.

(9) The substitution of any drug by a pharmacist or the pharmacist's employer pursuant to this section does not constitute the practice of medicine.

(10) A substitution of drugs made by a pharmacist or the pharmacist's employer in accordance with this section and any rules that the State Board of Pharmacy may adopt thereunder does not constitute evidence of negligence if the substitution was made within reasonable and prudent practice of pharmacy or if the substituted drug was accepted in a generally recognized formulary or government list.

(11) Failure of a practitioner to specify that no substitution is authorized does not constitute evidence of negligence unless the practitioner knows that the health condition of the patient for whom the practitioner is prescribing warrants the use of the brand name drug product and not the substituted drug. [1979 c.777 §35; 1983 c.402 §4; 1985 c.565 §110; 1987 c.108 §5; 1989 c.706 §22; 1991 c.734 §76; part renumbered 689.854 and 689.857 in 1991; 1993 c.534 §1; 1993 c.571 §14; 1999 c.350 §5; 2001 c.589 §1; 2001 c.623 §7a; 2009 c.326 §4]

689.520 [Amended by 1965 c.466 §2; 1967 c.291 §2; 1969 c.314 §89; 1969 c.514 §35; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.522 Substitution of biosimilar products for prescribed biological products. (1) As used in this section:

(a) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(b) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).

(c) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).

(d) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Administration to be interchangeable. [2013 c.342 §2; 2013 c.342 §4]

689.525 Out-of-state prescriptions. (1) A prescription written by a practitioner licensed in a state or territory of the United States, other than Oregon, may be filled only if the pharmacist called upon to fill such prescription determines, in the exercise of professional judgment:

(a) That it was issued pursuant to a valid patient-practitioner relationship; and

(b) That it is authentic.

(2) However, if the practitioner writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of the prescription.

(3) The provisions of ORS 689.515 authorizing generic substitution shall not apply to prescriptions described in this section unless authorized on the prescription. [1979 c.777 §36; 1981 c.666 §10; 1987 c.108 §6; 1993 c.571 §15; 1997 c.153 §1]

689.527 Prohibited practices; rules. (1) Except as approved by rule by the State Board of Pharmacy, a person may not dispense drugs to the public by means of automatic vending machines.

(2) As used in this section, "automatic vending machine" means any mechanical device or contrivance whereby the purchaser is able to secure drugs.

(3) A person may not adulterate for the purpose of sale any drug in such manner as to render it injurious to health, or knowingly sell or offer for sale any adulterated drug.

(4) A person may not manufacture, compound or sell or offer for sale or cause to be manufactured, compounded, sold or offered for sale any drug, compound or preparation for internal or external use under or by a name recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia or National Formulary which differs from the standard of strength and purity specified therein as official at the time of manufacture, compounding, sale or offering for sale.

(5) A person may not manufacture, compound, sell or offer for sale, or cause to be manufactured, sold or offered for sale, any drug, the strength and purity of which falls below the professed standard of strength and purity under which it is sold.

(6) A person may not sell, give away, barter, dispense, distribute, buy, receive or possess any prescription drug except as authorized by law.

(7) A manufacturer or wholesaler may not sell or otherwise distribute, or offer to sell or otherwise distribute, any drug or device except to a person legally authorized to resell, dispense or otherwise redistribute such drug or device. The board may grant an exemption from the requirement of this subsection in the form of a special permit if the board finds that an exemption is in the best interest of the public health and safety.

(8)(a) A person may not sell, purchase or trade or offer to sell, purchase or trade any drug sample.

(b) As used in paragraph (a) of this subsection, "drug sample" means a unit of a drug, subject to this chapter, that is not intended to be sold and is intended to promote the sale of the drug, and includes a coupon or other form which may be redeemed for a drug.

(9) For purposes of this section and ORS 678.375, distribution of prepackaged complimentary samples of medications by a nurse practitioner or clinical nurse specialist with prescription writing authority shall not constitute dispensing when the sample medication is within the prescriptive authority granted to that nurse practitioner or clinical nurse specialist. [Formerly 689.765]

689.530 [Amended by 1969 c.514 §36; 1977 c.688 §2; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.532 Complimentary samples. A practitioner who receives a complimentary sample of a controlled substance as defined in ORS 475.005 shall keep the sample in a securely locked, substantially constructed cabinet and shall maintain a record of receipts and withdrawals from each inventory of samples. Each licensing board that has jurisdiction over a practitioner's license shall specify the recording requirements for complimentary samples by rule. The licensing board may inspect the records and the inventory of samples. [2009 c.326 §8]

689.535 [1979 c.777 §37; 1981 c.217 §1; 1985 c.565 §111; repealed by 2003 c.102 §2]

689.540 [Amended by 1969 c.514 §37; 1977 c.688 §3; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.545 [1979 c.249 §1; 1981 c.388 §2; repealed by 2003 c.102 §2]

689.550 [Amended by 1965 c.466 §1; 1967 c.291 §3; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.555 Agricultural drugs, nonprescription drugs and certain other substances. (1) Nothing in this chapter prohibits the sale by any person of agricultural or garden spray, sheep dip, blue

stone, copperas, squirrel poison, fly paper, ant poison, gopher poison, insect powder, poultry vermifuge and arsenic sprays when they are in original unbroken packages, prepared and labeled with official poison labels and showing antidotes.

(2) Nothing in this chapter requires or authorizes the licensing or regulation of the sale of economic poisons, which includes any substance or mixture of substances intended to be used for preventing, destroying, repelling or mitigating any and all insects, fungi, weeds, parasites, or other plant or animal pest, collectively or individually, which may infest or be detrimental to vegetation or any domestic animal or fowl life. [1979 c.777 §40; 1985 c.565 §112]

689.557 Disposal of marijuana at retail drug outlets; rules; exemption from criminal liability. (1) The State Board of Pharmacy shall establish by rule instructions for the disposal of marijuana left behind by individuals visiting retail drug outlets.

(2) At a minimum, the instructions established under subsection (1) of this section must:

(a) Require an employee or supervisor of the retail drug outlet to notify law enforcement upon discovering marijuana at the site; and

(b) Include procedures for destroying the marijuana so that it can no longer be used for human consumption.

(3) A person acting under and in accordance with this section is exempt from the criminal laws of this state for any criminal offense in which possession of marijuana is an element. [2015 c.614 §131]

689.560 [Amended by 1969 c.514 §42; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.565 [1999 c.874 §§1,2,3,4; repealed by 2007 c.272 §13]

689.570 [Amended by 1969 c.514 §40; 1973 c.829 §69; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.580 [Amended by 1969 c.514 §45; repealed by 1973 c.743 §9 and by 1973 c.829 §71]

689.590 [Amended by 1965 c.580 §9; 1969 c.514 §44; 1973 c.427 §35; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.595 [1969 c.514 §43; repealed by 1973 c.427 §36 (689.596 enacted in lieu of 689.595)]

689.596 [1973 c.427 §37 (enacted in lieu of 689.595); repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.600 [Amended by 1969 c.514 §39; repealed by 1977 c.842 §45 and 1979 c.777 §59]

MISCELLANEOUS

689.605 Power to dispense drugs from hospital pharmacies, drug rooms and penal institutions; rules. (1) In a hospital or long term care facility having a pharmacy and employing a pharmacist, the pharmacy and pharmacist are subject to the requirements of this chapter, except that in a hospital when a pharmacist is not in attendance, pursuant to standing orders of the pharmacist, a registered nurse supervisor on the written order of a person authorized to prescribe a drug may withdraw such drug in such volume or amount as needed for administration to or

treatment of an inpatient or outpatient until regular pharmacy services are available in accordance with the rules adopted by the board. However, the State Board of Pharmacy may grant an exception to the requirement for a written order by issuing a special permit authorizing the registered nurse supervisor in a hospital to dispense medication on the oral order of a person authorized to prescribe a drug. An inpatient care facility which does not have a pharmacy must have a drug room. In an inpatient care facility having a drug room as may be authorized by rule of the Department of Human Services or the Oregon Health Authority, the drug room is not subject to the requirements of this chapter relating to pharmacies. However, a drug room must be supervised by a pharmacist and is subject to the rules of the State Board of Pharmacy. When a pharmacist is not in attendance, any person authorized by the prescriber or by the pharmacist on written order may withdraw such drug in such volume or amount as needed for administration to or treatment of a patient, entering such withdrawal in the record of the responsible pharmacist.

(2) In a hospital having a drug room, any drug may be withdrawn from storage in the drug room by a registered nurse supervisor on the written order of a licensed practitioner in such volume or amount as needed for administration to and treatment of an inpatient or outpatient in the manner set forth in subsection (1) of this section and within the authorized scope of practice.

(3) A hospital having a drug room shall cause accurate and complete records to be kept of the receipt, withdrawal from stock and use or other disposal of all legend drugs stored in the drug room. Such record shall be open to inspection by agents of the board and other qualified authorities.

(4) In an inpatient care facility other than a hospital, the drug room shall contain only prescribed drugs already prepared for patients therein and such emergency drug supply as may be authorized by rule by the Department of Human Services.

(5) The requirements of this section shall not apply to facilities described in ORS 441.065.

(6) A registered nurse who is an employee of a local health department that is registered by the board under ORS 689.305 may, pursuant to the order of a person authorized to prescribe a drug or device, dispense a drug or device to a client of the local health department for purposes of caries prevention, birth control or prevention or treatment of a communicable disease. Such dispensing shall be subject to rules jointly adopted by the board and the Oregon Health Authority.

(7) The board shall adopt rules authorizing a pharmacist to delegate to a registered nurse the authority to withdraw prescription drugs from a manufacturer's labeled container for administration to persons confined in penal institutions including, but not limited to, adult and juvenile correctional facilities. A penal institution, in consultation with a pharmacist, shall develop policies and procedures regarding medication management, procurement and distribution. A pharmacist shall monitor a penal institution for compliance with the policies and procedures and shall perform drug utilization reviews. The penal institution shall submit to the board for approval a written agreement between the pharmacist and the penal institution regarding medication policies and procedures. [1979 c.777 §38; 1979 c.785 §9d; 1985 c.565 §113; 1989 c.526 §1; 1993 c.272 §2; 1993 c.571 §16; 1995 c.523 §3; 2003 c.617 §2; 2009 c.595 §1103; 2015 c.736 §109]

689.610 [Amended by 1969 c.514 §41; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.615 Display of certificate or license; rules. (1) The holder of any certificate or license granted under this chapter shall display it conspicuously in the pharmacy or place of business to which it applies.

(2) All pharmacist certificates issued by the State Board of Pharmacy shall bear the signatures of all members and officers of the board.

(3) On payment by the applicant of the fee established by the board by rule under ORS 689.135, the board may issue a new certificate to a pharmacist if the applicant has lost the certificate or the certificate has been destroyed. [1979 c.777 §25; 1985 c.565 §114; 1987 c.108 §7; 1993 c.571 §17; 2013 c.514 §11]

689.620 [Amended by 1965 c.545 §4; 1969 c.514 §38; 1973 c.697 §10; 1975 c.686 §10; 1977 c.745 §45; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.625 [1975 c.686 §12; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.630 [Repealed by 1965 c.46 §1]

689.635 Dispensing according to naturopathic formulary; effect of filling prescription of naturopath. A drug prescribed by a naturopathic physician licensed under ORS chapter 685 in accordance with the formulary established by ORS 685.145 may be dispensed by a licensed pharmacist or an employee of a licensed pharmacist according to the terms of the prescription. The filling of a prescription under this section does not constitute evidence of negligence on the part of the pharmacist or the employee if the prescription is dispensed within the reasonable and prudent practices of pharmacy. [1989 c.945 §4; 1993 c.571 §18; 2009 c.420 §4]

689.640 [Repealed by 1969 c.514 §57]

689.645 Power to administer and prescribe vaccines, provide approved patient care services; rules. (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may:

(a) Administer vaccines:

(A) To persons who are seven years of age or older; or

(B) If authorized by the Governor under ORS 433.441 or the Public Health Director under ORS 433.443 or 433.444, to a person three years of age or older.

(b) Pursuant to a statewide drug therapy management protocol developed by the Oregon Health Authority and adopted by rule of the board, provide approved patient care services including smoking cessation therapy and travel health services.

(2) The board may adopt rules allowing a pharmacist to prescribe vaccines and provide patient care services under subsection (1) of this section. The rules related to the prescription of vaccines may be only as broad as necessary to enable pharmacists to enroll and participate in the Vaccines for Children Program administered by the Centers for Disease Control and Prevention.

(3) The board is authorized to issue, to licensed pharmacists who have completed training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body, certificates of special competency in the prescription and administration of vaccines.

(4) The board shall adopt rules relating to the reporting of the prescription and administration of vaccines to a patient's primary health care provider and to the Oregon Health Authority.

(5) The board shall adopt rules requiring pharmacists to establish protocols for the prescription and administration of vaccines and the provision of patient care services under subsection (1) of this section.

(6) The board shall convene a volunteer Public Health Advisory Committee consisting of no more than nine members for the purpose of advising the board in promulgating rules under this section. The committee shall consist of one representative from the Oregon Health Authority, two representatives from the Oregon Medical Board, two representatives from the Oregon State

Board of Nursing and two representatives from the State Board of Pharmacy. The committee may not include more than two pharmacists other than the representatives from the State Board of Pharmacy. [1999 c.350 §3b; 2005 c.312 §1; 2009 c.250 §1; 2009 c.595 §1104; 2011 c.245 §1; 2013 c.332 §5; 2015 c.295 §1; 2015 c.362 §4]

Note: Section 15, chapter 362, Oregon Laws 2015, provides:

Sec. 15. The name of the Immunization and Vaccination Advisory Committee is changed to the Public Health Advisory Committee. The Public Health Advisory Committee is a continuation of the Immunization and Vaccination Advisory Committee. [2015 c.362 §15]

689.650 [1965 c.545 §6; 1969 c.314 §90; 1969 c.514 §31; repealed by 1973 c.697 §21]

689.655 Power to administer drugs and devices; rules. A pharmacist may administer a drug or device if the pharmacist is acting:

(1) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; and

(2) In accordance with the rules adopted by the State Board of Pharmacy regarding the administration of drugs and devices. [1999 c.350 §3e; 2009 c.326 §5]

Note: Section 3f, chapter 350, Oregon Laws 1999, provides:

Sec. 3f. Nothing in this 1999 Act shall be construed to allow a pharmacist to prescribe drugs or to dispense or administer any drug or device that requires a prescription without a prescription or order of a practitioner authorized to prescribe drugs. [1999 c.350 §3f]

689.660 [1965 c.545 §7; 1971 c.650 §40; 1971 c.734 §141; 1973 c.697 §8; repealed by 1977 c.745 §54 and 1977 c.842 §45]

689.661 Power to perform tests and examinations related to federally cleared analytes. (1) A pharmacy may perform the tests and examinations described in subsection (2) of this section if the pharmacy obtains a waiver from the United States Department of Health and Human Services pursuant to 42 C.F.R. 493.35 and complies with the requirements of 42 C.F.R. 493.35, 493.37 and 493.39.

(2) Tests and examinations authorized under this section include any test or examination related to an analyte that the United States Food and Drug Administration has cleared under 42 C.F.R. 493.15. [2013 c.94 §2]

689.665 [1975 c.369 §§3,5; 1979 c.785 §10; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.670 [1975 c.686 §2; repealed by 1977 c.842 §43 and 1979 c.777 §59]

689.675 [1975 c.686 §3; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.680 [1975 c.686 §4; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.681 Opiate overdose; treatments; training; administration of naloxone; rules. (1) As used in this section:

(a) "Opiate" means a narcotic drug that contains:

(A) Opium;

(B) Any chemical derivative of opium; or

(C) Any synthetic or semisynthetic drug with opium-like effects.

(b) "Opiate overdose" means a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function and the impairment of the vital functions as a result of ingesting opiates in an amount larger than can be physically tolerated.

(2) The Oregon Health Authority shall establish by rule protocols and criteria for training on lifesaving treatments for opiate overdose. The criteria must specify:

(a) The frequency of required retraining or refresher training; and

(b) The curriculum for the training, including:

(A) The recognition of symptoms and signs of opiate overdose;

(B) Nonpharmaceutical treatments for opiate overdose, including rescue breathing and proper positioning of the victim;

(C) Obtaining emergency medical services;

(D) The proper administration of naloxone to reverse opiate overdose; and

(E) The observation and follow-up that is necessary to avoid the recurrence of overdose symptoms.

(3) Training that meets the protocols and criteria established by the authority under subsection (2) of this section must be subject to oversight by a licensed physician or certified nurse practitioner and may be conducted by public health authorities, organizations or other appropriate entities that provide services to individuals who take opiates.

(4) Notwithstanding any other provision of law, a pharmacy, a health care professional with prescription and dispensing privileges or any other person designated by the State Board of Pharmacy by rule may distribute unit-of-use packages of naloxone, and the necessary medical supplies to administer the naloxone, to a person who:

(a) Conducts training that meets the protocols and criteria established by the authority under subsection (2) of this section, so that the person may possess and distribute naloxone and necessary medical supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets the protocols and criteria established by the authority under subsection (2) of this section, so that the person may possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(5) A person who has successfully completed the training described in this section is immune from civil liability for any act or omission committed during the course of providing the treatment pursuant to the authority granted by this section, if the person is acting in good faith and the act or omission does not constitute wanton misconduct. [2013 c.340 §2]

689.683 Prescription and dispensation of certain contraceptives; rules; insurance coverage. (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe and dispense hormonal contraceptive patches and self-administered oral hormonal contraceptives to a person who is:

(a) At least 18 years of age, regardless of whether the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a hormonal contraceptive patch or self-administered oral hormonal contraceptive; or

(b) Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a hormonal contraceptive patch or self-administered oral hormonal contraceptive.

(2)(a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board, the Oregon State Board of Nursing and the Oregon Health Authority, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, standard

procedures for the prescribing of hormonal contraceptive patches and self-administered oral hormonal contraceptives by pharmacists.

(b) The rules adopted under this subsection must require a pharmacist to:

(A) Complete a training program approved by the State Board of Pharmacy that is related to prescribing hormonal contraceptive patches and self-administered oral hormonal contraceptives;

(B) Provide a self-screening risk assessment tool that the patient must use prior to the pharmacist's prescribing the hormonal contraceptive patch or self-administered oral hormonal contraceptive;

(C) Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and dispensing the hormonal contraceptive patch or self-administered oral hormonal contraceptive;

(D) Provide the patient with a written record of the hormonal contraceptive patch or self-administered oral hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(E) Dispense the hormonal contraceptive patch or self-administered oral hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

(c) The rules adopted under this subsection must prohibit a pharmacist from:

(A) Requiring a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive; and

(B) Prescribing and dispensing a hormonal contraceptive patch or self-administered oral hormonal contraceptive to a patient who does not have evidence of a clinical visit for women's health within the three years immediately following the initial prescription and dispensation of a hormonal contraceptive patch or self-administered oral hormonal contraceptive by a pharmacist to the patient.

(3) All state and federal laws governing insurance coverage of contraceptive drugs, devices, products and services shall apply to hormonal contraceptive patches and self-administered oral hormonal contraceptives prescribed by a pharmacist under this section. [2015 c.649 §2]

Note: The amendments to 689.683 by section 3, chapter 649, Oregon Laws 2015, become operative January 1, 2020. See section 6, chapter 649, Oregon Laws 2015. The text that is operative on and after January 1, 2020, is set forth for the user's convenience.

689.683 (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe and dispense hormonal contraceptive patches and self-administered oral hormonal contraceptives.

(2)(a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board, the Oregon State Board of Nursing and the Oregon Health Authority, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, standard procedures for the prescribing of hormonal contraceptive patches and self-administered oral hormonal contraceptives by pharmacists.

(b) The rules adopted under this subsection must require a pharmacist to:

(A) Complete a training program approved by the State Board of Pharmacy that is related to prescribing hormonal contraceptive patches and self-administered oral hormonal contraceptives;

(B) Provide a self-screening risk assessment tool that the patient must use prior to the pharmacist's prescribing the hormonal contraceptive patch or self-administered oral hormonal contraceptive;

(C) Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and dispensing the hormonal contraceptive patch or self-administered oral hormonal contraceptive;

(D) Provide the patient with a written record of the hormonal contraceptive patch or self-administered oral hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(E) Dispense the hormonal contraceptive patch or self-administered oral hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

(c) The rules adopted under this subsection must prohibit a pharmacist from:

(A) Requiring a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive; and

(B) Prescribing and dispensing a hormonal contraceptive patch or self-administered oral hormonal contraceptive to a patient who does not have evidence of a clinical visit for women's health within the three years immediately following the initial prescription and dispensation of a hormonal contraceptive patch or self-administered oral hormonal contraceptive by a pharmacist to the patient.

(3) All state and federal laws governing insurance coverage of contraceptive drugs, devices, products and services shall apply to hormonal contraceptive patches and self-administered oral hormonal contraceptives prescribed by a pharmacist under this section.

689.685 [1975 c.686 §5; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.690 [1975 c.686 §6; repealed by 1979 c.777 §59]

689.695 [1975 c.686 §7; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.705 [1955 c.326 §1; 1967 c.260 §1; repealed by 1969 c.514 §57]

689.710 [1955 c.326 §2; repealed by 1969 c.514 §57]

689.715 [1955 c.326 §3; 1967 c.345 §1; repealed by 1969 c.514 §57]

689.720 [1955 c.326 §4; 1957 c.350 §1; 1963 c.96 §7; 1967 c.183 §7; 1969 c.514 §21; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.725 [1955 c.326 §5; 1969 c.514 §28; 1973 c.743 §7; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.730 [1955 c.326 §6; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.735 [1955 c.326 §7; 1969 c.514 §22; renumbered 689.810]

689.740 [1955 c.326 §8; 1969 c.514 §23; renumbered 689.815]

689.745 [1955 c.326 §9; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.750 [1955 c.326 §10; 1969 c.514 §24; repealed by 1977 c.842 §45 and 1979 c.777 §59]

689.755 [1955 c.326 §11; repealed by 1969 c.514 §57]

689.760 [1955 c.326 §12; repealed by 1969 c.514 §57]

689.765 [1979 c.777 §39; 1985 c.131 §6; 1987 c.108 §8; 1987 c.736 §2; 1993 c.571 §19; 2003 c.103 §3; 2005 c.462 §9; 2008 c.4 §4; 2009 c.326 §6; renumbered 689.527 in 2009]

CHARITABLE PRESCRIPTION DRUG PROGRAM

689.770 Definitions for ORS 689.770 to 689.780. As used in ORS 689.770 to 689.780, "the Charitable Prescription Drug Program" means a drug outlet that has:

(1) A valid certificate of registration issued by the State Board of Pharmacy;

(2) Volunteered to participate in the Charitable Prescription Drug Program; and

(3) Been approved by the board to accept and distribute to needy individuals donated prescription drugs through the program. [2009 c.300 §2]

689.772 Establishment of program; immunity from liability; rules. (1) There is created in the State Board of Pharmacy the Charitable Prescription Drug Program. The purpose of the program is to distribute donated prescription drugs to needy or uninsured individuals. Participation in the program is voluntary.

(2) The program may accept and distribute:

(a) Prescription drugs received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3)(a) Except as provided in paragraph (b) of this subsection, the program may not distribute donated prescription drugs that:

(A) Fail to meet the requirements of this section;

(B) Bear an expiration date that is less than nine months from the date the drug is donated;

(C) Are adulterated or misbranded; or

(D) Belong to a category of controlled substances that may not be distributed under the program as adopted by the board by rule pursuant to ORS 689.774.

(b) The board may waive a requirement of this subsection if the board determines that the waiver is in the interest of public health and safety. A waiver under this subsection must be issued in writing in accordance with rules adopted by the board.

(4) The program shall:

(a) Require a donor of prescription drugs to complete and sign a donor form, adopted by rule by the board, releasing the prescription drug to the program for distribution under the program and certifying that the donated drug has been properly stored and has never been opened, used, adulterated or misbranded;

(b) Require that the pharmacist will use professional judgment, based on a visual inspection, to verify compliance with this section and rules adopted by the board under ORS 689.774;

(c) Properly dispose of all prescription drugs that do not meet the requirements of this section and rules adopted by the board under ORS 689.774;

(d) Maintain separate confidential files for individuals receiving donated prescription drugs through the program;

(e) Eliminate personal information from the labels of donated prescription drugs;

(f) Maintain an inventory of donated prescription drugs separate from any other inventory;

(g) Store donated prescription drugs in a secure location to be used exclusively for the program;

(h) Report to the board on the activities of the program in the form and manner required by the board; and

(i) Require a recipient of a donated prescription drug to sign a form, as adopted by the board by rule, attesting that the recipient has been notified by the program that:

(A) The prescription drug distributed to the recipient was donated to the program;

(B) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging;

(C) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the donor's form and the visual inspection by the pharmacist; and

(D) Participants in the program are immune from liability as provided in ORS 689.780.

(5) The program may not charge a fee for accepting a donation but may charge a fee established by the board by rule for distributing a prescription drug.

(6) The program may not sell any prescription drugs received as a donation through the program.

(7) The program may refuse to accept a prescription drug that, upon visual inspection, appears not to qualify for distribution under this section or rules adopted by the board under ORS 689.774.

(8) The program may distribute donated prescription drugs to:

(a) Another charitable prescription drug program; or

(b) An individual with a new prescription for prescription drugs who meets the requirements of ORS 689.778. [2009 c.300 §3; 2013 c.95 §1]

689.774 Rules. The State Board of Pharmacy shall adopt rules to carry out ORS 689.770 to 689.780, including but not limited to:

(1) Specifying categories of prescription drugs that the program may not distribute under the program;

(2) Prescribing the forms described in ORS 689.772;

(3) Establishing the criteria for licensure and regulation under the program;

(4) Establishing standards and procedures for accepting, storing, distributing, shipping and disposing of donated prescription drugs under the program;

(5) Establishing standards and procedures for inspecting donated prescription drugs to ensure that the drugs comply with the requirements of this section and ORS 689.772; and

(6) Establishing record keeping and reporting requirements for the program. [2009 c.300 §4]

689.776 Inspection; audit. The State Board of Pharmacy shall ensure compliance with ORS 689.770 to 689.780 by:

(1) Inspecting the Charitable Prescription Drug Program on a regular basis; and

(2) Auditing records required to be maintained by a pharmacy in connection with the program. [2009 c.300 §5]

689.778 Eligibility. An individual is eligible to obtain donated prescription drugs through the Charitable Prescription Drug Program created in ORS 689.772 if the individual:

(1) Is a resident of this state; and

(2)(a) Does not have health insurance coverage for the prescription drug requested;

(b) Is enrolled in a program of public assistance, as defined in ORS 411.010, or medical assistance, as defined in ORS 414.025; or

(c) Meets other requirements adopted by rule by the State Board of Pharmacy that identify needy individuals with barriers to accessing prescription drugs. [2009 c.300 §6; 2013 c.688 §92]

689.780 Immunity. (1) As used in this section, "participant" means:

(a) A person who donates a prescription drug to the Charitable Prescription Drug Program;

(b) The Charitable Prescription Drug Program;
(c) The State Board of Pharmacy;
(d) A pharmacist;
(e) A drug manufacturer; or
(f) A health practitioner.

(2) A participant who accepts or distributes donated prescription drugs through the Charitable Prescription Drug Program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith. [2009 c.300 §7]

689.805 [1969 c.514 §49; repealed by 1979 c.777 §59]

689.810 [Formerly 689.735; 1979 c.744 §62; repealed by 1979 c.777 §59]

689.815 [Formerly 689.740; 1975 c.484 §1; repealed by 1979 c.777 §59]

689.825 [1973 c.533 §2; 1975 c.369 §2; 1979 c.785 §11; repealed by 1979 c.777 §59]

689.830 [1975 c.218 §2; repealed by 1979 c.777 §59]

PENALTIES

689.832 Civil penalties. (1) In addition to any other liability or penalty provided by law, the State Board of Pharmacy may impose a civil penalty for any violation of the provisions of this chapter or ORS chapter 475 or any rule of the board. A civil penalty imposed under this subsection may not exceed $1,000 for each violation by an individual and $10,000 for each violation by a drug outlet.

(2) All penalties recovered under this section shall be deposited into the State Board of Pharmacy Account established in ORS 689.139.

(3) Any civil penalty under this section shall be imposed in the manner provided in ORS 183.745.

(4) Notwithstanding ORS 183.745, the person to whom the notice is addressed shall have 10 days from the date of service of the notice in which to make written application for a hearing before the board. [1981 c.217 §3; 1991 c.734 §77; 1993 c.571 §20; 1995 c.79 §348; 2005 c.726 §13; 2007 c.90 §2]

689.835 [1975 c.218 §3; 1979 c.785 §12; repealed by 1979 c.777 §59]

689.837 [1981 c.217 §4; repealed by 1993 c.571 §30]

689.840 [1975 c.218 §4; repealed by 1979 c.777 §59]

689.842 [1981 c.217 §5; repealed by 1993 c.571 §30]

689.845 [1975 c.218 §6; 1979 c.785 §13; repealed by 1979 c.777 §59]

689.847 [1981 c.217 §6; 1989 c.706 §23; repealed by 1991 c.734 §122]

689.850 [1975 c.218 §5; repealed by 1979 c.777 §59]

689.852 [1981 c.217 §7; 1991 c.734 §78; repealed by 1993 c.571 §30]

689.854 Civil penalty for violation of ORS 689.515. (1) In addition to all other penalties provided by law every person who violates ORS 689.515 or any rule adopted thereunder may incur a civil penalty of up to $250 for every such violation.

(2) The penalty imposed under this section may be remitted or mitigated upon such terms and conditions as the State Board of Pharmacy considers proper and consistent with the public health and safety.

(3) Civil penalties under this section shall be imposed as provided in ORS 183.745.

(4) Civil penalties recovered under this section shall be deposited into the State Board of Pharmacy Account established in ORS 689.139. [Formerly part of 689.515; 2005 c.726 §14]

689.855 [Formerly 453.310; repealed by 1979 c.777 §59]

689.857 [1981 c.217 §8; 1991 c.734 §79; subsection (2) formerly part of 689.515; repealed by 1993 c.571 §30]

689.860 [Formerly 453.320; repealed by 1979 c.777 §59]

689.865 [Formerly 453.020; 1973 c.743 §8; 1975 c.218 §7; 1979 c.785 §14; repealed by 1979 c.777 §59]

689.880 [1977 c.611 §3; repealed by 1979 c.777 §59]

689.885 [1977 c.611 §2; repealed by 1979 c.777 §59]

689.890 [1977 c.611 §4; repealed by 1979 c.777 §59]

689.895 [1977 c.255 §2; 1979 c.249 §2; repealed by 1979 c.777 §59]

689.990 [Subsection (12) of 1965 Replacement Part enacted as 1955 c.326 §13; 1967 c.158 §1; 1969 c.514 §54; repealed by 1979 c.777 §59]

689.992 [Repealed by 1967 c.158 §2]

689.995 Criminal penalties. (1) Violation of any provision of this chapter or of any rule of the State Board of Pharmacy is a misdemeanor.

(2) Failure to comply with any notice, citation or subpoena issued by the board under ORS 689.135 (12) is a misdemeanor. Each day during which the violation continues is a separate offense.

(3) Refusal to furnish information required under this chapter or willfully furnishing false information, is a misdemeanor.

(4) Any attempt to secure or the securing of registration or licensure for any person under any certificate, license or permit authorized by this chapter by making or causing to be made any false representations is a misdemeanor. [1979 c.777 §41; 1985 c.131 §7; 1985 c.565 §115; 1993 c.571 §22; 2011 c.597 §143]

The Oregon Administrative Rules contain OARs filed through January 15, 2017

BOARD OF PHARMACY

DIVISION 1 PROCEDURAL RULES 3
855-001-0010 Requiring an Answer to Charges as Part of Notices to Parties in Contested Cases . 4
855-001-0035 Duty to Cooperate 5
DIVISION 6 DEFINITIONS 7
DIVISION 7 PUBLIC HEALTH EMERGENCY 15
DIVISION 10 BOARD ADMINISTRATION AND POLICIES 23
Criminal Background Checks Employees, Applicants for Employment and Volunteers 26
DIVISION 11 HEALTH PROFESSIONAL'S SERVICE PROGRAM 35
DIVISION 19 LICENSING OF PHARMACISTS 39
Licensing 40
Pharmacist Practice 44
Pharmacist Care and Practice 48
Administration of Vaccines by Pharmacists 53
Pharmacist-in-Charge 55
Discipline 57
Prescriptive Authority 58
Delivery of Care 59
DIVISION 21 CONTINUING PHARMACY EDUCATION 63
DIVISION 25 CERTIFIED PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS 67
DIVISION 31 INTERNSHIP REGULATIONS 75
DIVISION 35 OPERATION OF NONPRESCRIPTION AND MEDICAL DEVICE, EQUIPMENT AND GAS (MDEG) OUTLETS 81
DIVISION 41 OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS) 85
General 87
Licensure 94
Prescriptions 95
Labeling 99
Dispensing 102
Records 102
General Community Pharmacy 105
Distribution of Emergency Medication 106
Central Fill Drug Outlets, Remote Processing Drug Outlets and Consulting or Drugless Pharmacies 109
Central Fill Drug Outlets 109
Remote Processing Drug Outlets 114
Consulting or Drugless Pharmacies 117
Expedited Partner Therapy 120
Prescription 121
Labeling 121
Counseling 121
Records 122
Retail Drug Outlet for Home Dialysis Supplies 122
Remote Dispensing 124
Remote Distribution Facilities 127
Residential Drug Outlets 127
Technician Checking Validation Program (TCVP) 128
Hospitals with Pharmacies 133
Drug Distribution and Control 135
Absence of a Pharmacist 139

Outpatient Drug Distribution 140
Labeling 142
Automated Dispensing Machine 143
In-Patient Drug Distribution 144
Floor-stock and Non–emergency Trays and Kits 150
Controlled Substances 150
Hospitals with Drug Rooms 153
Pharmacists Serving Long Term Care Facilities and Community Based Care Facilities 156
Home Health Care Agencies 159
DIVISION 42 NUCLEAR PHARMACIES AND PHARMACISTS 161
DIVISION 43 PRACTITIONER DISPENSING 165
Nurse Practitioner Dispensing 166
Supervising Physician Dispensing Outlets 167
Correctional Facilities 172
Community Health Clinic Drug Outlet 176
Policies and Procedures 177
DIVISION 44 CHARITABLE PHARMACIES 181
DIVISION 45 STERILE AND NON-STERILE COMPOUNDING 189
DIVISION 50 RESTRICTION ON RETAIL SALES 201
DIVISION 60 PHARMACEUTICAL MANUFACTURERS 203
DIVISION 62 DRUG DISTRIBUTION AGENT 211
DIVISION 65 WHOLESALE DRUG OUTLETS 219
DIVISION 70 PROPHYLACTICS AND CONTRACEPTIVES 233
DIVISION 80 SCHEDULE OF CONTROLLED SUBSTANCES 235
Registration of Manufacturers, Distributors and Dispensers 239
Controlled Substances Prescriptions 241
DIVISION 110 FEES 245

BOARD OF PHARMACY

DIVISION 1
PROCEDURAL RULES

855-001-0000
Notice of Proposed Rule

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

(1) In a manner established by rule adopted by the Board under ORS183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;
(2) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;

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

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

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

(a) Oregon State Pharmacist Association;

(b) Oregon Society of Health System Pharmacists;

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

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

855-001-0005
Model Rules of Procedure

Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective July 1, 2014. These rules 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 183.341 & 689.205
Stats. Implemented: ORS 183.341
Hist.: 1PB 25, f. 3-20-72, ef. 4-15-72; 1PB 31, f. 11-20-73, ef. 12-11-73; 1PB 42, f. & ef. 4-6-76; Renumbered from 855-010-0030; 1PB 7-1978(Temp), f. & ef. 7-1-78; 1PB 9-1978, f. & ef. 10-23-78; 1PB 1-1980, f. & ef. 1-21-80; 1PB 3-1981, f. & ef. 12-15-81; PB 2-1987, f. & ef. 3-30-87; PB 5-1988, f. & cert. ef. 10-17-88; PB 4-1992, f. & cert. ef. 8-25-92; PB 1 -1996, f. & cert. ef. 4-5-96; BP 1-2001, f. & cert. ef. 3-5-01; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 5-2004, f. & cert. ef. 10-1-04; BP 13-2006, f. & cert. ef. 12-19-06; BP 3-2008, f. & cert. ef. 7-1-08; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

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

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

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

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

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

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

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

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

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

(b) A short and plain statement of each relevant affirmative defense the party may have.
(2) Except for good cause:

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

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

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

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

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

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

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

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

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

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

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

855-001-0035
Duty to Cooperate

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

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

855-001-0040
Inspections

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

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

(b) Inspecting within reasonable limits and a reasonable manner all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and labeling found at the drug outlet;
(c) Making a physical inventory of all drugs on hand at the premises;

(d) Collecting samples of drugs or ingredients;

(e) Checking of records and information on distribution of drugs by the registrants as they relate to total distribution of the registrant;
(f) All other things appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Uniform Controlled Substances Act, the Oregon Pharmacy Act and these rules.

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

(3) Refusal to allow inspection is grounds for denial, suspension, or revocation of a registration.
Stat. Auth.: ORS 475.125 & ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; Renumbered from 855-080-0060, BP 1-2007, f. & cert. ef. 6-29-07

BOARD OF PHARMACY

DIVISION 6
DEFINITIONS

855-006-0005
Definitions As used in OAR chapter 855:

(1) “Board” means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

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

(3) “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(4) "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.

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

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

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

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

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

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

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

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

(9) "Dispensing or Dispense" 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.

(10) "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.

(11) "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.

(12) "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.

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

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

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

(16) "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.

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

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

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

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

(A) Over-utilization or under-utilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug dosage;

(F) Incorrect duration of treatment;

(G) Drug-allergy interactions; and

(H) Clinical drug abuse or misuse.

(19) "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.

(20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the specialized education program pursuant to OAR 855-025-0012.

(21) “Practice of clinical pharmacy” means:

(a) The health science discipline in which, in conjunction with the patient’s other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient’s health and wellness;

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

(22) “Practice of pharmacy” is as defined in ORS 689.005.

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

(24) “Prohibited conduct” means conduct by a licensee that:

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

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

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

(a) Assure retention of their purity and potency;

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

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

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

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

(26) “Quality Assurance Plan” is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.

(27) "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.

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

(a) Dispensing;

(b) Drug utilization review;

(c) Claims adjudication;

(d) Refill authorizations;

(e) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only; and

(f) Therapeutic interventions.

(29) "Specialized Education Program" means;

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

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

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

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

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

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

(31) "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.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005, 689.151, 689.155, 689.305, 689.405 & 689.455, 689.645
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; PB 2-1988, f. & cert. ef. 5-3-88; PB 2-1989, f. & cert. ef. 1-30-89; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; BP 4-1998, f. & cert. ef. 8-14-98; BP 1-2006, f. & cert. ef. 6-9-06; BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10; BP 3-2012, f. & cert. ef. 6-19-12; BP 8-2015, f. & cert. ef. 12-23-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-006-0015
Additional Definitions

(1) Electronically Transmitted Prescription:

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

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

(B) Transmission from a computer to another computer;

(C) Transmission by facsimile to computer; or

(D) Transmission from a computer to facsimile.

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

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

(2) Tamper-resistant Prescription:

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

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

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

(B) Background ink which reveals attempted alterations;

(C) Heat sensitive ink that changes colors;

(D) Penetrating ink to prevent chemical alterations;

(E) A watermark which cannot be photocopied;

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

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

855-006-0020
Unprofessional Conduct Defined

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

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

(A) Customers, patients or the public;

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

(C) Insurance companies;

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

(E) Health care facilities;

(F) Government agencies; or

(G) Drug outlets.

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

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

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

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

(A) Type of drug prescribed;

(B) Amount prescribed; or

(C) When prescribed out of context of dose.

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

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

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

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

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

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

Stat. Auth.: 689.205
Stats. Implemented: ORS 689.005 and 689.155
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

BOARD OF PHARMACY

DIVISION 7
PUBLIC HEALTH EMERGENCY

855-007-0010
Declaration of Emergency

(1) With the exception of OAR 855-007-0060(2)(a) and (b), 855-007-0080(2), 855-007-0080(8)(a) and (b), and 855-007-0120 that are always in effect, the rules in this Division are only effective when:
(a) A State of Emergency or a Public Health Emergency has been declared by the Governor of Oregon under ORS 401.055 or 433.441 through 433.452;

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

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

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

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

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

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

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

855-007-0020
Applicability

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

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

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

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

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

855-007-0030
Definitions

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

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

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

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

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

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

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

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

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

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

(11) “Oregon State Public Health Division” (OSPHD) means that division of the Oregon Department of Human Services (DHS) that is responsible for planning for and responding to a public health emergency.
(12) “Pacific Northwest Emergency Management Arrangement” (PNEMA) means the compact, ratified in Chapter 25 Oregon Laws 2008, between the states of Alaska, Idaho, Oregon and Washington, and the Province of British Columbia, and Yukon, to provide mutual assistance in an emergency or public health emergency.

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

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

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

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

855-007-0040
Delegation of Authority

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

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

855-007-0050
Emergency Licensure

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

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

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

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

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

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

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

(D) Any other information requested by the Board.

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

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

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

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

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

855-007-0060
SNS and State Stockpile Emergency Drugs

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

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

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

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

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

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

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

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

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

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

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

(C) Date repackaged;

(D) Quantity of drugs in the regimen;

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

(F) Number for 24-hour telephone line;

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

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

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

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

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

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

855-007-0080
Emergency Immunization and Drug Distribution

When a public health emergency has been declared, the following principles and procedures shall apply to the distribution, dispensing and administration of vaccines or drugs:

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

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

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

(a) A LHD;
(b) A clinician;
(c) A community health clinic;
(d) An independent or chain pharmacy;
(e) A hospital or other health-care facility;
(f) A temporary pharmacy;
(g) A mobile pharmacy; or
(h) A tribal health-care facility.

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

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

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

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

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

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

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

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

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

(d) A Community Partner shall:

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

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

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

(i) The name and age of the person receiving the drugs;
(ii) The name, strength and quantity of the drugs;
(iii) The date and the time of the distribution.

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

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

(10) A pharmacist may administer a vaccine to a person who is at least three years of age or older.

Stat. Auth.: ORS 401.065, 433.441, 689.205 & 2013 OL Ch 332
Stats. Implemented: 689.155 & 2013 OL Ch 332
Hist.: BP 4-2008(Temp), f. 12-31-08, cert. ef. 1-5-09 thru 7-3-09; BP 1-2009, f. & cert. ef. 6-22-09; BP 4-2009, f. & cert. ef. 12-24-09; BP 2-2014, f. & cert. ef. 1-24-14

855-007-0090
Emergency Pharmacy Rules

(1) Refills: A pharmacist in the area covered by a declared emergency or in an area engaged in disaster assistance may dispense a refill of a prescription drug without a valid prescription provided that:
(a) In the pharmacist's professional judgment, the drug is essential to the maintenance of the patient's health or the continuation of therapy; and

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

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

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

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

(2) New and modified drug therapy: A pharmacist in the area covered by a declared emergency or in an area engaged in disaster assistance may, after consultation with any authorized prescriber, initiate or

modify any drug therapy, and dispense an amount of the drug to meet the patient's health needs until that patient can be seen by a health-care practitioner, provided that:

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

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

(c) The pharmacist records all relevant information to a form and indicates that a drug therapy has been initiated or modified and that this is an Emergency Prescription; and
(d) The pharmacist informs the patient or the patient's agent at the time of dispensing that the drug is being provided in the absence of a valid patient — prescriber relationship but that a prescriber was consulted regarding the appropriateness of the drug therapy; and

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

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

855-007-0100
Temporary Pharmacies

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

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

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

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

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

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

855-007-0110
Emergency Recordkeeping
All records initiated during a state of emergency shall be disposed of as follows:

(1) POD intake forms and Individual Data Collection Forms or electronic records shall be transferred to OSPHD at the end of the emergency;
(2) Community Partner's Logs:

(a) Vaccines: Logs shall be transferred to OSPHD within 14 days of administration to be entered into the statewide immunization information system. If the Community Partner is a registered health-care facility or under the control of a licensed health-care provider, a copy of the log shall be made before submission and retained for three years.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BOARD OF PHARMACY

DIVISION 10
BOARD ADMINISTRATION AND POLICIES

855-010-0001
Definitions

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

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

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

855-010-0005
Meetings

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

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

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

(a) Approval of ACPE programs;

(b) Approval of preceptor sites;

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

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

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

855-010-0015
Individual Commitments

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

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

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

855-010-0021
Adoption by Reference

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

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

855-010-0035
Board Compliance Program

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

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

855-010-0045
State and Nationwide Criminal Background Checks

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

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

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

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

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

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

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

(A) Any drug or alcohol offence;

(B) Any felony;

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

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

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

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

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

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

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

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

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

(D) The subsequent commission of another relevant crime;

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

(F) A recommendation of an employer.

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

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

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

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

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

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

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

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

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

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

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

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

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

Criminal Background Checks
Employees, Applicants for Employment and Volunteers

855-010-0050
Purpose

The purpose of these rules is to provide for the reasonable screening of subject individuals to determine if they have a history of criminal behavior such that they are not fit to work or volunteer for the Board. The fact that the Board determines that a subject individual is fit does not guarantee the individual a position as a Board employee, volunteer, or that the individual will be hired by the Board.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0055
Definitions

As used in OAR 855-010-0050 through 855-010-0086, unless the context of the rule requires otherwise, the following definitions apply:

(1) Conviction: A final judgment on a verdict or finding of guilty, a plea of guilty, or a plea of nolo contendere (no contest) or any determination of guilt entered by a court of law against a subject individual in a criminal case, unless that judgment has been reversed or set aside by a subsequent court decision.

(2) Fitness determination: A determination made by the Board, pursuant to the process established under OAR 855-010-0060, that a subject individual is fit or not fit to be a Board employee or volunteer.

(3) Criminal offender information: Records and related data concerning physical description and vital statistics, fingerprints received and compiled by the Oregon State Police (OSP) to identify criminal offenders and alleged offenders, records of arrests and the nature and disposition of criminal charges, including sentencing, confinement, parole and release records.

(4) Criminal records check: One or more of the following three processes undertaken by the Board to check the criminal history of a subject individual:

(a) A name-based check of criminal offender information conducted through the Law enforcement Data System (LEDS) maintained by the OSP, in accordance with the rules adopted and procedures established by the OSP;

(b) A check of Oregon criminal offender information, through fingerprint identification and other means, conducted by the OSP at the Board's request (Oregon Criminal Records Check); or

(c) A nationwide check of federal criminal offender information, through fingerprint identification and other means, conducted by the OSP through the FBI or otherwise at the Board's request (Nationwide Criminal Records Check).

(5) Criminal Records Request form: A Board-approved form, completed by a subject individual, requesting the Board to conduct a criminal records check.

(6) False statement: In association with an activity governed by these rules, a subject individual either:

(a) Provided the Board with false information about the subject individual’s criminal history, including but not limited to false information about the individual’s identity or conviction record; or

(b) Failed to provide the Board information material to determining the individual’s criminal history.

(7) Subject Individual: An individual identified in OAR 855-010-0057 as someone from whom the Board may require a criminal records check.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0057
Subject Individual

The Board may require a subject individual to complete a criminal records check pursuant to these rules because the person is:

(1) A Board employee

(2) A Board volunteer; or

(3) An applicant for employment with the Board.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0060
Criminal Records Check Process

(1) Disclosure of Information by Subject Individual.

(a) Preliminary to a criminal records check, a subject individual must complete and sign the Board Criminal Records Request form and a fingerprint card. Both forms ask for identifying information (e.g., name, birth date, social security number, physical characteristics, driver's license or identification card number and current address of the subject individual). The Board Criminal Records Request form also requires information about the subject individual's prior residences in other states and any other identifying information deemed necessary by the Board.

(b) A subject individual must complete and submit to the Board the Criminal Records Request form and, if requested, a fingerprint card within five business days of receiving the forms. The Board may extend the deadline for good cause.

(c) The Board may require additional information from the subject individual as necessary to complete the criminal records check and fitness determination, such as, but not limited to, proof of identity, or additional criminal, judicial, or other background information.

(d) The Board shall not request a fingerprint card from a subject individual under the age of 18 years unless the subject individual is emancipated pursuant to ORS 419B.550 et seq, or unless the Board also requests the written consent of a parent or guardian. In such case, such parent or guardian and youth must be informed that they are not required to consent. Notwithstanding, failure to consent may be construed as a refusal to consent under OAR 855-010-0065(3).

(2) When a Criminal Records Check is required. The Board may conduct, or request the OSP to conduct, a criminal record check when:

(a) An individual meets the definition of a subject individual; or

(b) Required by federal law or regulation, by state statute or administrative rule, or by contract or written agreement with the Board.

(3) Which Criminal Records Check is conducted. When the Board determines under section (2) of this rule that a criminal records check is needed, the Board may request or conduct a LEDS Criminal Records Check, an Oregon Criminal Records Check, a Nationwide Criminal Records Check, or any combination thereof.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0065
Final Fitness Determination

(1) If the Board elects to conduct a criminal records check, the Board shall make a fitness determination about a subject individual based on information provided by the subject individual under OAR 855-010-0060(1), any criminal records check conducted, and any false statement made by the subject individual.

(2) In making a fitness determination about a subject individual, the Board will also consider the factors in subsections (a) through (f) below in relation to information provided by the subject individual under OAR 855-010-0060(1), any LEDS report or criminal offender information obtained through a criminal records check, and other information known by the Board. To assist in considering these factors, the Board may obtain any other information deemed relevant from the subject individual or any other source, including

law enforcement and criminal justice agencies or courts within or outside of Oregon. To acquire other criminal offender information from the subject individual, the Board may request to meet with the subject individual, and may request to receive written materials or authorization to obtain other relevant information, from the subject individual. The subject individual shall meet with the Board if requested and provide additional information or authorization within a reasonable period of time, as established by the Board. The Board will use all collected information in considering:

(a) Whether the subject individual has been convicted, found guilty except for insanity (or a comparable disposition), or has a pending indictment for a crime listed in OAR 855-010-0067;

(b) The nature of any crime identified under section (2)(a) of this rule;

(c) The facts that support the conviction, finding of guilty except for insanity, or pending indictment;

(d) Any facts that indicate the subject individual made a false statement;

(e) The relevance, if any, of a crime identified under section (2)(a) of this rule or of a false statement made by the subject individual to the specific requirements of the subject individual's present or proposed position, services or employment; and

(f) The following intervening circumstances, to the extent that they are relevant to the responsibilities and circumstances of the services or employment for which the fitness determination is being made:

(A) The passage of time since the commission or alleged commission of a crime identified under section (2)(a) of this rule;

(B) The age of the subject individual at the time of the commission or alleged commission of a crime identified under section (2)(a) of this rule;

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

(D) The subsequent commission of another crime listed in OAR 855-010-0067;

(E) Whether a conviction identified under section (2)(a) of this rule has been set aside, and the legal effect of setting aside the conviction;

(F) A recommendation of an employer;

(G) The disposition of a pending indictment identified under section (2)(a) of this rule;

(H) Whether the subject individual has been arrested for or charged with a crime listed under OAR 855-010-0067;

(I) Whether the subject individual is being investigated, or has an outstanding warrant, for a crime listed under OAR 855-010-0067;

(J) Whether the subject individual is currently on probation, parole or another form of post-prison supervision for a crime listed under 855-010-0067;

(K) Whether the subject individual has a deferred sentence or conditional discharge in connection with a crime listed under OAR 855-010-0067;

(L) Whether the subject individual has been adjudicated in a juvenile court and found to be within the court's jurisdiction for an offense that would have constituted a crime listed in OAR 855-010-0067if committed by an adult;

(M) Periods of incarceration of the subject individual;

(N) The education and work history (paid or volunteer) of the subject individual since the commission or alleged commission of a crime.

(3) Refusal to Consent. If a subject individual refuses to submit or consent to a criminal records check including fingerprint identification, the Board will deny the employment of the subject individual or deny any applicable position or authority to provide services. A person may not appeal any determination made based on a refusal to consent.

(4) If a subject individual is determined to be not fit, the subject individual may not be employed by or provide services as a volunteer to the Board.

(5) Final Order. A completed final fitness determination is a final order of the Board unless the affected subject individual appeals the determination by requesting a contested case hearing as provided by OAR 855-010-0080(2) or an alternative appeals process as provided by OAR 855-010-0080(6).

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0067
Potentially Disqualifying Crimes

(1) Crimes Relevant to a Fitness Determination:

(a) All felonies;

(b) All misdemeanors;

(c) Any United States Military crime or international crime;

(2) Evaluation of Crimes. The Board shall evaluate a crime on the basis of the law of the jurisdiction in which the crime or offense occurred, as those laws are in effect at the time of the fitness determination.

(3) Expunged Juvenile Record. Under no circumstances shall a subject individual be determined to be not fit under these rules on the basis of the existence or contents of a juvenile record that has been expunged pursuant to ORS 419A.260 and ORS 419A.262.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0070
Incomplete Fitness Determination

(1) The Board will close a preliminary or final fitness determination as incomplete when:

(a) Circumstances change so that a person no longer meets the definition of a "subject individual" under OAR 855-010-0057;

(b) The subject individual does not submit materials or information within the time required under OAR 855-010-0060;

(c) The Board cannot locate or contact the subject individual;

(d) The subject individual fails or refuses to cooperate with the Board's attempts to acquire other criminal records information under OAR 855-010-0065; or

(e) The Board determines that the subject individual is not eligible or not qualified for the position of employee or volunteer, for a reason unrelated to the fitness determination process.

(f) The position is no longer open.

(2) A subject individual does not have a right to a contested case hearing under OAR 855-010-0080(2) or a right to an alternative appeals process under OAR 855-010-0080(6) to challenge the closing of a fitness determination as incomplete.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0075
Notice to Subject Individual of Fitness Determination

The Board shall inform the subject individual who has been determined not to be fit on the basis of a criminal records check, via personal service, or registered or certified mail to the most current address provided by the subject individual, of such disqualification.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0080
Appealing a Fitness Determination

(1) Purpose: Sections (2) to (5) of this rule set forth the contested case hearing process a subject individual must use to appeal a completed final fitness determination made under OAR 855-010-0065 that the individual is not fit to hold a position with, or provide services to the Board as an employee or volunteer. Section (6) of this rule identifies an alternative appeal process available only to current Board employees.

(2) Appeal process.

(a) To request a contested case hearing, the subject individual or the subject individual's legal representative must submit a written request for a contested case hearing to the address specified in the notice provided under OAR 855-010-0075. To be timely, the request must be received by the Board at the specified address within 14 calendar days of the date stated on the notice. The Board shall address a request received after expiration of the deadline as provided under OAR 137-003-0528.

(b) When a timely request is received by the Board under subsection (a), a contested case hearing shall be conducted by an administrative law judge assigned by the Office of Administrative Hearings, pursuant to the Attorney General's Uniform and Model Rules, “Procedural Rules, Office of Administrative Hearings” OAR 137-003-0501 to 137-003-0700, as supplemented by the provisions of this rule.

(3) Discovery. The Board or the administrative law judge may protect information made confidential by ORS 181.534(15) or other applicable law as provided under OAR 137-003-0570(7) or (8).

(4) No Public Attendance. Contested case hearings on fitness determinations are closed to non-participants.

(5) Proposed and Final Order:

(a) Proposed Order. After a hearing, the administrative law judge will issue a proposed order.

(b) Exceptions. Exceptions, if any, shall be filed within 14 calendar days after service of the proposed order. The proposed order shall provide an address to which exceptions must be sent.

(c) Default. A completed final fitness determination made under OAR 855-010-0065 becomes final:

(A) Unless the subject individual makes a timely request for a hearing; or

(B) When a party withdraws a hearing request, notifies the Board or the ALJ that the party will not appear, or fails to appear at the hearing.

(6) Alternative Process. A subject individual currently employed by the Board may choose to appeal a fitness determination either under the process made available by this rule or through a process made available by applicable personnel rules, policies and collective bargaining provisions. A subject individual's decision to appeal a fitness determination through applicable personnel rules, policies, and collective bargaining provisions is an election of remedies as to the rights of the individual with respect to the fitness determination and is a waiver of the contested case process made available by this rule.

(7) Remedy. The only remedy that may be awarded is a determination that the subject individual is fit or not fit. Under no circumstances shall the Board be required to place a subject individual in any position, nor shall the Board be required to accept services or enter into a contractual agreement with a subject individual.

(8) Challenging Criminal Offender Information. A subject individual may not use the appeals process established by this rule to challenge the accuracy or completeness of information provided by the OSP, the FBI, or agencies reporting information to the OSP or the FBI.

(a) To challenge information identified in this section of the rule, a subject individual may use any process made available by the agency that provided the information.

(b) If the subject individual successfully challenges the accuracy or completeness of information provided by the OSP, the FBI, or an agency reporting information to the OSP or the FBI, the subject individual may request that the Board conduct a new criminal records check and re-evaluate the original fitness determination made under OAR 855-010-0065 by submitting a new Board Criminal Records Request form. This provision only applies if the position for which the original criminal history check was conducted is vacant and available.

(9) Appealing a fitness determination under section (2) or section (6) of this rule, challenging criminal offender information with the agency that provided the information, or requesting a new criminal records check and re-evaluation of the original fitness determination under section (8)(b) of this rule, will not delay or postpone the Board’s hiring process or employment decisions.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0085
Recordkeeping and Confidentiality

Any information obtained in the criminal records check is confidential. The Board must restrict the dissemination of information obtained in the criminal records check. Only those persons, as identified by the Board, with a demonstrated and legitimate need to know the information, may have access to criminal records check records.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0087
Fees

(1) The Board may charge a fee for acquiring criminal offender information for use in making a fitness determination that will not exceed the fee charged the Board by the OSP and the FBI to obtain such information.

(2) The Board may charge the fee to the subject individual on whom criminal offender information is sought.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

BOARD OF PHARMACY

DIVISION 11
HEALTH PROFESSIONAL'S SERVICE PROGRAM

855-011-0005
Definitions

When used in this division of rules:

(1) “Health Professionals’ Service Program (the Program)” means the impaired health professional program established by the Oregon Health Authority pursuant to authority granted by ORS 676.190.

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10; BP 12-2010, f. & cert. ef. 12-23-10

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

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

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

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

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

Stat. Auth.: ORS 689.205 & 2013 OL Ch 367
Stats. Implemented: ORS 676.200 & 2013 OL Ch 367
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10; BP 12-2010, f. & cert. ef. 12-23-10; BP 2-2014, f. & cert. ef. 1-24-14

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

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

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

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

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

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

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

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

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

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

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

(a) Licensee's disciplinary history;

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10; BP 12-2010, f. & cert. ef. 12-23-10

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

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

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

(b) Possesses a master's degree or a doctorate in a mental health discipline;

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10; BP 12-2010, f. & cert. ef. 12-23-10

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

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 676.200
Hist.: BP 7-2010(Temp), f. & cert. ef. 6-29-10 thru 12-24-10; BP 12-2010, f. & cert. ef. 12-23-10

BOARD OF PHARMACY

DIVISION 19
LICENSING OF PHARMACISTS

855-019-0100
Application

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

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.255
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

855-019-0110
Definitions

In this Division of Rules:

(1) “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

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

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

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

(5) "Drug Utilization Review (DUR)" has the same meaning as defined in OAR 855-006-0005.
(6) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

(7) “Practice of Clinical Pharmacy” means:

(a) The health science discipline in which, in conjunction with the patient’s other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient’s health and wellness;

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

(8) “Practice of Pharmacy” is as defined in ORS 689.005.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005, 689.151, 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 8-2015, f. & cert. ef. 12-23-15

Licensing

855-019-0120
Licensure

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

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

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. This score shall remain valid for only one year unless the Board grants an extension. A candidate who does not attain this score may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times.

(c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy approved by the Board. A candidate who does not attain this score may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times. The MPJE score shall be valid for 6 months unless extended by the Board;

(d) Complete an application for licensure, provide the Board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check.

(2) A license, once obtained, will expire on June 30 in odd numbered years and must be renewed biennially.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; 1PB 3-1985, f. & ef. 12-2-85; PB 3-1991, f. & cert. ef. 9-19-91; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0005, BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 6-2016, f. & cert. ef. 12-14-16

855-019-0122
Renewal of Licensure as a Pharmacist

(1) An application for renewal of a pharmacist license must include documentation of:

(a) Completion of continuing education requirements as prescribed in chapter 855, division 21; and

(b) Payment of the biennial license fee as prescribed in OAR 855-110.

(2) A pharmacist will be subject to an annual criminal background check.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151
Hist.: BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

855-019-0125
Coaching from Board and Staff

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

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

855-019-0130
Licensure by Reciprocity

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

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

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

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

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

(e) Have either:

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

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

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

(3) An applicant who has obtained their professional degree outside the United States is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-019-0150.
Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151 & 689.265
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1981, f. & ef. 8-20-81; 1PB 1-1984, f. & ef. 2-16-84; PB 1-1989, f. & cert. ef. 1-3-89; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-019-0015 & 855-019-0030, BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 6-2014(Temp), f. & cert. ef. 4-25-14 thru 10-22-14

855-019-0140
NAPLEX Score Transfer

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

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

(3) An applicant must provide the following documentation:

(a) Oregon Score Transfer Application;

(b) A passport regulation photograph;

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

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

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

855-019-0150
Foreign Pharmacy Graduates

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

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151 & 689.255
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 3-2014(Temp), f. 2-27-14, cert. ef. 2-28-14 thru 8-27-14; BP 7-2014, f. & cert. ef. 6-18-14

855-019-0160
Nuclear Pharmacists

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

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

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

(3) Submit to the Board of Pharmacy either:

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

(b) Evidence that they meet both the following:

(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and
(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the Board.

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

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

855-019-0170
Reinstatement of License

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

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

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

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

(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151 & 689.275
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1981, f. & ef. 8-20-81; BP 1-2002, f. & cert. ef. 1-8-02; Renumbered from 855-019-0040, BP 2-2008, f. & cert. ef. 2-20-08; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

855-019-0171
Reinstatement of a Revoked or Surrendered License

A person whose pharmacist license has been revoked or surrendered shall have the right, at reasonable intervals, to petition to the Board in writing for reinstatement of such license. The written petition to the Board shall be made in conjunction with the application process identified in OAR 855-019-0120.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151 & 689.275
Hist.: BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

Pharmacist Practice

855-019-0200
General Responsibilities of a Pharmacist

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

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

(2) Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:

(a) Drug Utilization Review;

(b) Counseling;

(c) Drug Regimen Review;

(d) Medication Therapy Management;

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;

(f) Practice pursuant to State Drug Therapy Management Protocols;

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

(h) Oral receipt or transfer of a prescription; and

(i) Final verification of the work performed by those under their supervision.

(3) A pharmacist may not delegate any task listed in OAR 855-019-0200(2), except that a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties.

(4) An intern cannot perform final verification.

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

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

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

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

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

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.025, 689.151, 689.155
Hist.: PB 15-1989, f. & cert. ef. 12-26-89; PB 2-1997(Temp), f. 10-2-97, cert. ef. 10-4-97; BP 2-1998, f. & cert. ef. 3-23-98; Renumbered from 855-041-0210, BP 2-2008, f. & cert. ef. 2-20-08; BP 6-2010, f. & cert. ef. 6-29-10; BP 8-2015, f. & cert. ef. 12-23-15

855-019-0205
Duty to Report

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

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

(3) A pharmacist must report to the Board within 10 days if they:
(a) Are convicted of a misdemeanor or a felony; or

(b) If they are arrested for a felony.

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

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

(6) A pharmacist who has reasonable grounds to believe that any violation of these rules has occurred, must notify the Board within 10 days. However, in the event of a significant drug loss or violation related to drug theft, the pharmacist shall notify the Board within one (1) business day.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: 689.151, 689.155 & 689.455
Hist.: BP 6-2010, f. & cert. ef. 6-29-10; BP 2-2014, f. & cert. ef. 1-24-14; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

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

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

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

(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and not result solely from a questionnaire or an internet-based relationship; and

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

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

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

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

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

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

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

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

(f) The direction for use;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

855-019-0220
Drug Utilization Review (DUR)

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

(a) Full name of the patient for whom the drug is prescribed;
(b) Address and telephone number of the patient;
(c) Patient's gender, age or date of birth;

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

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

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

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

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

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

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

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

855-019-0230
Counseling

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

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

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

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

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

(e) For a prescription delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist;

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

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

(3) A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgment, a form of counseling other than oral counseling would be more effective.
(4) A pharmacist or intern shall initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

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

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

855-019-0240
Consulting Pharmacist Practice

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

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

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

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

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

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

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

(c) Provide educational materials or programs as requested.

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

855-019-0250
Medication Therapy Management

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

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between practitioner and pharmacist; and

(e) Improving outcomes.

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

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

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

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

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

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

(f) Monitoring the patient for adverse drug events;
(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication;

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

(A) Provide accountability and an audit trail; and

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

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

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

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

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

855-019-0260
Collaborative Drug Therapy Management

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Hist.: Hist.: BP 4-1998, f. & cert. ef. 8-14-98; BP 1-1999(Temp), f. & cert. ef. 1-29-99 thru 7-28-99; Administrative correction 8-9-99; BP 1-2000, f. & cert. ef. 2-16-00; Renumbered from 855-041-0400, BP 2-2008, f. & cert. ef. 2-20-08; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

855-019-0264

State Drug Therapy Management Protocols

(1) A pharmacist may participate in statewide drug therapy management protocols developed by the Oregon Health Authority to provide approved patient care services including but not limited to:

(a) Smoking cessation therapy;

(b) Travel health services; and

(c) Immunizations.

(2) The pharmacy must maintain written or electronic policies and procedures for each state drug therapy management protocol in which it participates.

(3) A pharmacist who participates in a state drug therapy management protocol must:

(a) Retain the required training documentation set forth by the protocol and make available to the Board upon request; and

(b) Document the prescription, administration, and patient interaction in the patient's record, and provide notification to the patient's primary care provider when available.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 2015 OL Ch. 362
Hist.: BP 8-2015, f. & cert. ef. 12-23-15

855-019-0265
Administration of Drugs

(1) In accordance with ORS 689.655, a pharmacist may administer a drug or device as specified in this rule.

(2) A pharmacist who administers a drug or device must:

(a) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device; and

(b) Ensure a record is kept for three years of such activities. This record shall include but is not limited to:

(A) Patient identifier;

(B) Drug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration;

(E) Pharmacist identifier.

(3) The pharmacist must be acting:

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice or;

(b) In accordance with a written protocol or collaborative drug therapy agreement with a licensed practitioner.

(4) The pharmacist must be able to document that they have received training on the drug or device to be administered and the route of administration. Such training may include a program approved by the ACPE, curriculum based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the Board.

(5) The pharmacist may administer a drug or device in conjunction with training the patient or the patient's caregiver how to administer or self-administer the drug or device.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.655
Hist.: BP 3-2011, f. & cert. ef. 4-18-11

Administration of Vaccines by Pharmacists

855-019-0270
Qualifications

(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.

(2) A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.

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

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

(b) The pharmacist training includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population the pharmacist treats;

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

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

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

(4) A pharmacist otherwise in compliance with section three of this rule may, during a declared emergency, administer a vaccine to a person who is at least three (3) years of age when;

(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

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

Stat. Auth.: ORS 689.205 433.441, 433.443 & 2015 OL Ch 295
Stats. Implemented: ORS 689.151, 689.155, 689.645 & 2015 OL Ch 295
Hist.: BP 7-2000, f. & cert. ef. 6-29-00; BP 3-2006, f. & cert. ef. 6-9-06; BP 1-2007, f. & cert. ef. 6-29-07; Renumbered from 855-041-0500, BP 2-2008, f. & cert. ef. 2-20-08; BP 11-2010, f. 10-22-10, cert. ef. 1-1-11; BP 2-2014, f. & cert. ef. 1-24-14; BP 8-2015, f. & cert. ef. 12-23-15

855-019-0280
Protocols, Policies and Procedures

(1) Prior to administering a vaccine to a person who is at least 7 years of age a pharmacist must follow protocols written and approved by the Oregon Health Authority (OHA) for administration of vaccines and the treatment of severe adverse events following administration of a vaccine.

(2) A pharmacist during a declared emergency may administer a vaccine to a person who is at least three (3) years of age when;

(a) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(b) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

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

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

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

(6) The pharmacist may prescribe, administer or dispense immunizations, including oral vaccines, as established by written protocols approved by OHA.

Stat. Auth.: ORS 689.205, 433.441, 433.443 & 2015 OL Ch 295
Stats. Implemented: ORS 689.151, 689.155, 689.645 & 2015 OL Ch 295
Hist.: BP 7-2000, f. & cert. ef. 6-29-00; BP 3-2006, f. & cert. ef. 6-9-06: Renumbered from 855-041-0510, BP 2-2008, f. & cert. ef. 2-20-08; BP 11-2010, f. 10-22-10, cert. ef. 1-1-11; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12; BP 2-2014, f. & cert. ef. 1-24-14; BP 8-2015, f. & cert. ef. 12-23-15

855-019-0290
Record Keeping and Reporting

(1) A pharmacist who administers a vaccine to a patient must fully document the administration in the patient's permanent record.

(2) A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider.

(a) The name, address, gender and date of birth of the patient;

(b) The date of administration of the vaccine;

(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;

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

(e) The phone number of the patient when available;

(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;

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

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

(5) For the purpose of participation in the Oregon Vaccines for Children program,

(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and

(b) The pharmacist is recognized as a prescriber.

(6) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.645
Hist.: BP 7-2000, f. & cert. ef. 6-29-00; BP 3-2006, f. & cert. ef. 6-9-06: Renumbered from 855-041-0520, BP 2-2008, f. & cert. ef. 2-20-08; BP 11-2010, f. 10-22-10, cert. ef. 1-1-11; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

Pharmacist-in-Charge

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

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

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

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

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

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

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

(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the Board within 15 days of the occurrence, on a form provided by the Board;
(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

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

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;
(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board;

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

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

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

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

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

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

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

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

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

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

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

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all

controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

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

Discipline

855-019-0310
Grounds for Discipline

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

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

(2) Repeated or gross negligence;

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

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

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

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

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

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

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

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

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

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

Prescriptive Authority

855-019-0400
Purpose
The purpose of rules OAR 855-019-0400 through 855-019-0435, operative January 1, 2016, is to develop standard procedures for the prescribing of hormonal contraceptive patches and oral contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules of this section, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a self-screening risk assessment questionnaire and standard procedural algorithm.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0405
Definitions

In OAR 855-019-0400 through 855-019-0435:

(1) “Clinical visit” means a consultation with a healthcare provider, other than a pharmacist, for women’s health, which should address contraception and age-appropriate screening.

(2) “Hormonal contraceptive patch” means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.

(3) “Oral hormonal contraceptive” means a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16; BP 1-2016, f. 4-28-16, cert. ef. 5-1-16

855-019-0410
Prescriptive Practice Consultation

In an effort to clarify, improve, and support appropriate pharmacist prescribing, the Board shall periodically review prescribing standards, practices, and scope in consultation with designated representatives from the Oregon Medical Board, Oregon State Board of Nursing, and Oregon Health Authority. The Board will seek recommendations from these representatives to be considered in conjunction with American Congress of Obstetricians and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to evaluate and improve prescribing practices within pharmacy. To the extent that developed standards are incorporated into practice, the forms, screening tools, or requisite training materials shall be prepared by the Board in consultation with these designated representatives.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0415
Training Program

(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe hormonal contraceptive patches and self-administered oral hormonal contraceptives for a patient.

(2) A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion.

(3) A pharmacist must maintain the certificate of completion and make available upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

Delivery of Care

855-019-0420
Age Requirements

(1) A pharmacist may prescribe hormonal contraceptive patches and self-administered oral hormonal contraceptives to a person who is:

(a) At least 18 years of age; or

(b) Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a hormonal contraceptive patch or self-administered oral hormonal contraceptive.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0425
Procedural Mandates

(1) For each new patient requesting contraceptive services and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:

(a) Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and

(b) Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient assessment; and

(c) Prescribe, if clinically appropriate, the hormonal contraceptive patch or self-administered oral hormonal contraceptive, or refer to a healthcare practitioner; and

(d) Provide the patient with a Visit Summary; and

(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(f) Document the encounter and maintain records pursuant to OAR 855-019-0435.

(2) If the hormonal contraceptive patch or self-administered oral hormonal contraceptive is dispensed, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.

(3) Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed pursuant to this process, per the request of the patient.

(4) A pharmacy must:

(a) Keep records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years; and

(b) Keep records of the medication dispensed for a minimum of three years; and

(c) Establish, maintain and enforce written procedures for the provision of care under this section, including, but not limited to:

(A) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and

(B) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0430
Prohibited Practices

A pharmacist must not:

(1) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive;

(2) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit;

(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires referral to a provider; and

(4) Prescribe to self or immediate family members.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0435
Records

(1) A pharmacist must document the encounter and the prescription, and maintain records of drug dispensing.

(2) A pharmacy must maintain records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and maintain records of the medication dispensed for a minimum of three years.

(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 2015 OL Ch. 649
Hist.: BP 7-2015(Temp), f. & cert. ef. 11-6-15 thru 5-3-16

855-019-0450
Purpose
The purpose of OAR 855-019-0450 through 855-019-0460 is to develop standard procedures for the prescribing and recordkeeping of naloxone by a pharmacist in Oregon.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
Hist.: BP 5-2016(Temp), f. & cert. ef. 9-7-16 thru 3-5-17; BP 6-2016, f. & cert. ef. 12-14-16

855-019-0455
Qualifications

A pharmacist educated in opiate overdose and naloxone rescue can prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone for an individual who:

(1) Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medical supplies to persons who successfully complete the training; or

(2) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
Hist.: BP 5-2016(Temp), f. & cert. ef. 9-7-16 thru 3-5-17; BP 6-2016, f. & cert. ef. 12-14-16

855-019-0460
Delivery of Care

(1) A pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose training to an OHA authorized person or organization.

(2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual who has successfully completed an OHA approved training. The pharmacist shall determine that the individual seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(3) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(4) The pharmacist shall dispense the naloxone product in a properly labeled container identifying the authorized recipient.

(5) Naloxone may not be dispensed without providing oral counseling to the authorized recipient, to include dose, effectiveness, adverse effects, storage conditions, and safety.

(6) The pharmacist must document the encounter and the prescription, and maintain records for three years.

(7) The pharmacy providing naloxone services must establish, maintain, and enforce written procedures including, but not limited to:

(a) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and

(b) Documentation and recordkeeping.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
Hist.: BP 5-2016(Temp), f. & cert. ef. 9-7-16 thru 3-5-17; BP 6-2016, f. & cert. ef. 12-14-16

BOARD OF PHARMACY

DIVISION 21
CONTINUING PHARMACY EDUCATION

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

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed three (3) continuing pharmacy education units (CEU's) in an approved continuing pharmacy education program prior to submission of the license renewal. Ten contact hours equals 1 CEU. Fifty minutes equals 1 contact hour.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.285
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

855-021-0010
Continuing Pharmacy Education

(1) In this rule the terms below have the meanings given:

(a) “Patient Safety” means procedures and processes that ensure that the correct patient receives the correct drug in the correct dose, and is counseled appropriately.

(b) “Medication error prevention” means procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose.

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

(a) A program shall consist of therapeutics, or pharmacy and drug law or other aspects of health care. A minimum of at least two hours of continuing education credit must be earned in the area of pharmacy and drug law. A minimum of two hours of continuing education credit must be earned in the area of patient safety or medication error prevention.

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

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

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

(a) Name of provider or sponsor;

(b) Type of program offered;

(c) Description of subject matter;

(d) Number of contact hours offered;

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

(f) Method of determining satisfactory completion of program;

(g) Dates and location of program;

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

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

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

(6) Continuing pharmacy education credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

(7) A maximum of 20 contact hours (2.0 CEU) may be earned in any licensing cycle by preparing and presenting CE programs. Pharmacists presenting CE programs may earn one contact hour (0.1 CEU) for preparation time of one hour or more, plus credit for the actual contact hour time of the presentation. A pharmacist must show content of the course, and a description of the intended audience (e.g., pharmacists, physicians, nurses). Public service programs, such as presentations to school children or service clubs, are not eligible for continuing education credit.

(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 may approve up to 26 contact hours of CE credit for pharmacists who have successfully completed nationally certified Disease State Management courses.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.285
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 2-1984, f. & ef. 3-7-84; 1PB 1-1986, f. & ef. 6-5-86; PB 10-1987, f. & ef. 12-8-87; PB 3-1991, f. & cert. ef. 9-19-91; PB 4-1992, f. & cert. ef. 8-25-92; BP 5-2000(Temp), f. 6-20-00, cert. ef. 6-20-00 thru 10-27-00; Administrative correction 6-21-01; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04; BP 12-2010, f. & cert. ef. 12-23-10; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

855-021-0016
Continuing Education in Pain Management

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

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

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

(2) A pharmacist must complete the required continuing education within 24 months of their first license renewal.

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

(4) The pain management continuing education required under this rule shall count towards the 3.0 continuing pharmacy education units required under OAR 855-021-0005, in the license cycle in which the pain management continuing education is completed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.285, 409.560 & 409.565
Hist.: BP 7-2006(Temp) f. & cert. ef. 8-25-06 thru 1-20-07; BP 11-2006, f. & cert. ef. 12-19-06; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

855-021-0025
Continuing Pharmacy Education -- Reciprocity

A pharmacist reciprocating into Oregon will not be required to submit proof of continuing pharmacy education during the initial license cycle.

Stat. Auth.: ORS 689.285
Stats. Implemented: ORS 689.205
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

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

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

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

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

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

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

855-021-0045
Notification of Annual License Renewal

(1) The Board will develop an appropriate biennial renewal notice to be issued to all licensed pharmacists prior to May 1 of each odd numbered year.

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.275
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

855-021-0050
Renewal Application

(1) The biennial renewal application must be submitted to the Board with the appropriate fee and the pharmacist must attest that he/she has satisfactorily completed the continuing pharmacy education requirements.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.275
Hist.: 1PB 45, f. & ef. 7-6-76; 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 1-2002, f. & cert. ef. 1-8-02; BP 2-2004, f. 5-21-04 cert. ef. 6-1-04; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

855-021-0055
Reinstatement

(1) Any person petitioning for reinstatement of a pharmacist license as provided within ORS 689.445 shall produce certification of the continuing education requirements of all years in which the license has been inactive prior to restoration of the license.

(2) Retired pharmacists who wish to reinstate their license should refer to OAR 855-019-0170(2).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.445
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; BP 11-2014, f. 12-30-14, cert. ef. 7-1-15

BOARD OF PHARMACY

DIVISION 25
CERTIFIED PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-025-0001
Purpose and Scope
The purpose of the Pharmacy Technician (PT) license is to provide an opportunity for an individual to obtain competency in the role as a Pharmacy Technician. This license will allow an individual time to take and pass a national pharmacy technician certification examination, which is required to be eligible for licensure as a Certified Oregon Pharmacy Technician (CPT). These rules facilitate the initial licensure of a nationally certified Pharmacy Technician seeking licensure in Oregon.

Stat. Auth.: 689.205
Stats. Implemented: 689.225, 689.486
Hist.: BP 8-2005, f. 12-14-05, cert. ef. 12-15-05; BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

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

(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has obtained a high school diploma or GED.

(2) Section one does not apply to persons under the age of 18 licensed by the Board as a Pharmacy Technician prior to January 1, 2015.

(3) An applicant for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician must complete an application for licensure, provide the Board with a valid e-mail address and furnish documentation required to conduct a criminal background check.

(4) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory Board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the Board determines that licensure will pose no danger to patients or to the public interest.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225, 689.486
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-025-0010
Licensure as a Pharmacy Technician

(1) The license of a Pharmacy Technician expires the second June 30 from the date of issue and is not to exceed two years.

(2) The Pharmacy Technician license is not renewable.

(3) A time limited extension of a Pharmacy Technician license may be granted once by petition to the Board. The written completed petition must be received by the Board prior to the expiration of the PT license.

(4) An individual may reapply for a Pharmacy Technician license if the previous PT license is lapsed for a period greater than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225, 689.486
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 4-2015, f. & cert. ef. 7-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-025-0012
Licensure as a Certified Oregon Pharmacy Technician

(1) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must demonstrate that he or she has taken and passed a national pharmacy technician certification examination offered by:

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

(b) The National Healthcareer Association (NHA).

(2) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and must be renewed biennially.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225, 689.486
Hist.: BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

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

(1) A person who has taken and passed a national pharmacy technician certification examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to in these rules as, and is licensed as a “Certified Oregon Pharmacy Technician.”

(2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:

(a) Pay the biennial license fee prescribed in OAR 855-110.

(b) Satisfactorily complete a minimum of 20 continuing pharmacy educating hours during the period from July 1 through June 30, of each license renewal cycle. These hours must include:

(A) Two hours of continuing pharmacy education in pharmacy law;

(B) Two hours of continuing pharmacy education in patient safety or error prevention; and

(C) Sixteen other hours of continuing pharmacy education or documented onsite training approved by the Board.

(c) OAR 855-025-0015(2)(b) does not apply to a Certified Oregon Pharmacy Technician applying for the first 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.

(d) Be subject to an annual criminal background check.

(3) The Board may randomly select and audit applications for renewal to verify completion of continuing education or documented onsite training reported on the application for renewal. A Certified Oregon Pharmacy Technician whose application for renewal is selected for audit must provide documentation of completion of the continuing pharmacy education reported.
(4) Effective January 1, 2015, national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(5) A Certified Oregon Pharmacy Technician who fails to renew his or her license by the expiration date and whose license has been lapsed for less than one year may renew his or her license as follows:

(a) Complete the renewal process;

(b) Pay the biennial license fee as prescribed in OAR 855-110;

(c) Pay a delinquent fee; and

(d) Complete the required continuing education pursuant to OAR 855-025-0015(2)(b).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225, 689.486
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 6-2015(Temp), f. & cert. ef. 8-21-15 thru 2-16-16; BP 8-2015, f. & cert. ef. 12-23-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

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

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

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

(3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must report to the Board within 10 days if they:

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

(b) If they are arrested for a felony.

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

(5) A Pharmacy Technician or Certified Oregon Pharmacy Technician who reports to a Board in good faith as required by section (4) of this rule is immune from civil liability for making the report.

(6) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the Board within 1 day.

(7) A Pharmacy Technician or Certified Oregon Pharmacy Technician must notify the Board in writing, within 15 days, of any change in email address, employment location or residence address except that a Pharmacy Technician who is employed at more than one pharmacy need only report the name and address of the pharmacy at which the technician normally works the most hours.
(8) A Certified Oregon Pharmacy Technician must obtain certificates of completion that show the date and number of hours earned to document continuing pharmacy education credit earned and must keep the certificates of completion for three years from the date of the program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.455
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 6-2010, f. & cert. ef. 6-29-10; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

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

(1) A Pharmacist or pharmacy may use Pharmacy Technicians or Certified Oregon Pharmacy Technicians only as authorized by the rules of the Board.

(2) Pharmacy Technicians or Certified Oregon Pharmacy Technicians must be supervised by a Pharmacist.

(3) Pharmacists, Pharmacist Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians must be clearly identified as such to the public.

(4) Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.

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

(6) Training:

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

(b) The pharmacist-in-charge must ensure the continuing competency of Pharmacy Technicians or Certified Oregon Pharmacy Technicians.

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

855-025-0030
Confidentiality

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

(2) A licensee may disclose patient information:

(a) To the Board;

(b) To a practitioner, Pharmacist, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by a Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or well-being; or

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

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

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

(2) The pharmacy must maintain on file and post the current license of each Pharmacy Technician or Certified Oregon Pharmacy Technician.

(3) Before allowing any person to work as a Pharmacy Technician or Certified Oregon Pharmacy Technician, the pharmacy and Pharmacist shall verify that the person is currently licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician.

(4) Prior to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician, a person must provide to the Pharmacist or pharmacist-in-charge a copy of the person's current Pharmacy Technician license or current Certified Oregon Pharmacy Technician license.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

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

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

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

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

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

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

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

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

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

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

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

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

(j) Bulk Compounding. Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.

(k) Preparation of parenteral products as follows:

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

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

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

(3) In order to protect the public, safety, health and welfare, Pharmacy Technicians or Certified Oregon Pharmacy Technicians shall not:
(a) Communicate or accept by oral communication a new or transferred prescription of any nature;

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

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

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

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

(f) Engage in the practice of pharmacy as defined in ORS 689.015.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

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

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

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

(2) Repeated or gross negligence in performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician;

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

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

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

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

(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a Pharmacy Technician or Certified Oregon Pharmacy Technician license;

(8) Allowing an individual to engage in the duties of a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician without a license or to use falsely the title of Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician;

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

(10) Failure to appropriately perform the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician as outlined in OAR 855-025-0040 while assisting a Pharmacist in the practice of pharmacy as defined in ORS 689.005;
(11) Any act or practice relating to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician which is prohibited by state or federal law or regulation; or

(12) Any conduct or practice by a Pharmacy Technician, Certified Oregon Pharmacy Technician or pharmacy that the Board determines is contrary to the accepted standards of practice.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151 & 689.405
Hist.: BP 9-2005, f. 12-14-05, cert. ef. 12-15-05; BP 1-2006, f. & cert. ef. 6-9-06; BP 6-2010, f. & cert. ef. 6-29-10; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

855-025-0060
Reinstatement of a Certified Oregon Pharmacy Technician License

(1) A Certified Oregon Pharmacy Technician who fails to renew their license by the deadline and whose license has been lapsed for greater than one year may reinstate their license as follows:

(a) Complete a new application for licensure and provide the Board with a valid e-mail address;

(b) Pay the biennial license fee as prescribed in OAR 855-110;

(c) Submit to a national fingerprint background check; and

(d) Provide certification of completion of 10 continuing education hours. These hours may not be counted toward renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

(C) Eight other hours of pharmacy technician-specific continuing education.

(2) A Certified Oregon Pharmacy Technician whose license has been lapsed greater than five years must:

(a) Re-take and pass a national pharmacy technician certification examination offered by:

(A) The Pharmacy Technician Certification Board (PTCB); or

(B) National Healthcareer Association (NHA).

(b) Satisfy reinstatement requirements pursuant to OAR 855-025-0060(1).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.225, 689.486
Hist.: BP 1-2006, f. & cert. ef. 6-9-06; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

BOARD OF PHARMACY

DIVISION 31
INTERNSHIP REGULATIONS

855-031-0005
Definitions

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

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

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

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

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

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

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

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

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

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

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

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

855-031-0010
Intern License Application

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

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

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

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

(a) A completed application;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 689.151 & 689.205
Stats. Implemented: ORS 689.207, 689.255 & 2009 OL Ch. 536
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 1-1994, f. & cert. ef. 2-2-94; BP 1-2001, f. & cert. ef. 3-5-01; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

855-031-0020
Intern Requirements and Responsibilities

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

(a) Traditional Pharmacy-practice Internship (TPI): an intern may not work in a TPI until after satisfactorily completing the first academic year in a school of pharmacy. An intern working in a TPI must be supervised by a licensed pharmacist or pharmacist preceptor;

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

(c) Other Internship.

(2) An intern may not work more than 48 hours per week in SRIs and must comply with all supervision and ratio requirements.

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

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

(5) An intern who is working in a pharmacy or other place of business must conspicuously display their intern license in the pharmacy or place of business and must be clearly identified as an intern at all times.

(6) An intern may perform only the duties listed in Division 25 of this Chapter before completion of the first academic year in a school of pharmacy.

(7) An intern may, after successful completion of their first academic year, perform the duties of an intern listed in Division 019 of this Chapter, but only after successful completion of coursework corresponding to those duties at their school of pharmacy and only with the permission of their supervising pharmacist.

(8) An intern is responsible for his or her own actions and must comply with all Board regulations.

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

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

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

(a) Convicted of a misdemeanor or a felony; or

(b) Arrested for a felony.

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

(13) If needed by an intern for compliance with another Board's requirement, an intern must maintain written or electronic records that support the number of TPI hours claimed by an intern and have those hours certified by a preceptor.

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

Stat. Auth.: ORS 689.151, 689.205
Stats. Implemented: 689.255 & 2009 OL Ch. 536
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 7-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1994, f. & cert. ef. 2-2-94; PB 3-1994, f. & cert. ef. 7-1-94; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

855-031-0026
Ratio & Supervision

(1) A pharmacist may not supervise more than one intern at a time at a TPI site who performs the duties of an intern as listed in OAR 855-019-0200(3)(g). A pharmacist may supervise more than one intern if only one intern performs the duties of an intern as listed in OAR 855-019-0200(3)(g) and if other interns supervised by the pharmacist perform the duties listed in OAR 855-025-0040.

(2) A preceptor may not supervise more than two interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the Board.

(3) With the written approval of a school of pharmacy, and when in their professional judgment it is appropriate, a preceptor may supervise up to 10 interns at public-health outreach programs such as informational health fairs that provide general information but not direct patient care.

(4) For immunization clinics, an immunizing pharmacist may supervise up to two immunizing interns.

(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed pharmacist or preceptor.

(6) The majority of an intern's overall experience must be with a licensed pharmacist preceptor.

Stat. Auth.: ORS 689.151, 689.205
Stats. Implemented: 689.255 & 2009 OL Ch. 536
Hist.: BP 9-2011, f. 12-30-11, cert. ef. 1-1-12

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

(1) In order for an Oregon intern to obtain credit for SRI experiences outside the State of Oregon, an intern must:

(a) Be licensed as required by state laws and rules in the state in which they will practice;

(b) Meet or exceed the minimum SRI requirements of the Board;

(2) In order for an out-of-state intern to practice in the State of Oregon, the intern must meet all requirements of these rules.

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

855-031-0045
School and Preceptor Registration and Responsibilities

(1) A preceptor license may be issued by the Board upon receipt of a completed application.

(2) A pharmacist preceptor must have been an actively practicing pharmacist for at least one year immediately prior to supervising an intern.

(3) A preceptor license must be renewed biennially and will expire on June 30 in odd numbered years.

(4) The preceptor may report to the Board voluntarily, the progress and aptitude of an intern under the preceptor's supervision, or must do so upon request of the Board.

(5) The preceptor must be responsible for supervision of the majority of the intern's SRI hours and must provide the intern with internship experiences, which in the preceptor's judgment will increase the intern's competency in the practice of pharmacy.

(6) Before supervising an intern in an SRI program, a preceptor must complete any training program required by the school of pharmacy.

(7) A preceptor must advise each school of pharmacy when they are supervising students from more than one school at the same time. This applies to both in-state and out-of-state schools or colleges of pharmacy.

(8) A preceptor must verify that their intern is currently licensed with the Board.

(9) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a pharmacist in Oregon, but is required to be licensed as a preceptor with the Board.

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

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

(12) All records related to a student must be available for three years after the student graduates.

Stat. Auth.: ORS 689.151 & 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; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2004, f. & cert. ef. 3-12-04; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12; BP 1-2015(Temp), f. & cert. ef. 4-10-15 thru 10-6-15; BP 4-2015, f. & cert. ef. 7-1-15

855-031-0050
Eligibility for Exams -- Foreign Pharmacy Graduates

In addition to the other requirements of this Division, a foreign pharmacy graduate must complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR 855-019-0150. Evidence of completing this requirement must be provided to the Board by the applicant and must be authenticated by each preceptor.

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

855-031-0055
Eligibility for Exams and Pharmacist Licensure

(1) An intern is eligible to take the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, upon graduation and notification to the Board by the school of pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.

(2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in the State of Oregon, a person must:

(a) Complete an application for licensure including providing any fingerprint card or other documentation required by the Board to conduct a criminal background check;

(b) Pay the license fee as prescribed in OAR 855-110; and

(c) Obtain a license, which will expire on June 30 in odd numbered years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135, 689.207, 689.225 & 689.275
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89; PB 5-1990, f. & cert. ef. 4-12-90; PB 7-1990, f. & cert. ef. 12-5-90; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2007, f. & cert. ef. 6-29-07; BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 1-2015(Temp), f. & cert. ef. 4-10-15 thru 10-6-15; BP 4-2015, f. & cert. ef. 7-1-15

BOARD OF PHARMACY

DIVISION 35
OPERATION OF NONPRESCRIPTION AND MEDICAL DEVICE, EQUIPMENT AND GAS (MDEG) OUTLETS

855-035-0005
Applications

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

(2) Application shall specify the location of the proprietary drug outlet. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(c) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(3) All registration renewal applications shall be accompanied by the annual fee and contain the same information required in subsections (2)(a), (b) and (c) of this rule.

(4) If the annual registration fee referred to in section (1) of this rule is not paid by January 31 of the current year, a delinquent fee as set forth in OAR 855-110-0007 shall be included with the application for registration renewal.

(5) A change of ownership or location requires a new application, fee and registration within 15 days of the change .

(6) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(7) The registration fee cannot be prorated.

(8) No nonprescription drug or medical gas authorized to be sold at retail under this registration shall be sold, given away, or otherwise disposed of until application has been approved and a certificate of registration issued. There shall be four types of drug outlet registrations:

(a) Class A shall be for all outlets except those that own more than one vending machine distributing more than six nonprescription drugs.

(b) Class B shall be for all outlets except those that own more than one vending machine distributing six or less nonprescription drugs.

(c) Class C shall be for all outlets distributing medicinal gases.

(d) Class D shall be for all outlets with more than one vending machine distributing nonprescription drugs.

(e) Class E shall be for any nonprofit, tax exempt, food distribution facility that distributes food products and nonprescription drugs at no cost, other than nominal delivery charges, to charitable organizations including regional food banks, for distribution at no cost to individuals. This registration, which shall be issued at no cost to the registrant, expires on January 31st annually.

Explanation: The intention of this section is that an owner of a single vending machine that contains over-the-counter medications can register as either a Class A or Class B outlet based on the number of medications in the machine. The owner of more than one vending machine that contains over-the-counter medications shall register as a Class D outlet and inform the Board of their locations. Class E registration is intended for the Oregon Food Bank and other regional food banks located in Oregon.

(9) If there is more than one drug outlet under the same roof and each outlet is independently operated by different owners, a separate registration shall be obtained for each outlet.

(10) In case of loss of the certificate of registration, the Board may require a sworn statement before a notary public to be filed in the Board office before duplicate certificates of registration can be issued.

(11) Each vending machine that contains nonprescription drugs must have an obvious and legible statement on the machine that identifies the owner of the machine, advises the customer to check the expiration date of the product before using, and lists the phone number for the Board of Pharmacy.

(12) A Class D nonprescription drug outlet shall keep the Board informed in writing of the current location of all of its vending machines.

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

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented: ORS 475.035, 689.135 & 689.305
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 2-2008, f. & cert. ef. 2-20-08

855-035-0007
Sales

Sales by drug outlets except itinerant vendors shall be made only from the premises at the location registered by the Board.

Stat. Auth.: ORS 475.035 & 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 or donate 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. A nonprescription drug outlet shall not purchase or receive nonprescription drugs from a source not registered with the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.135, 689.305 689.315
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96; BP 2-2008, f. & cert. ef. 2-20-08

855-035-0023
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 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
Medical Device, Equipment and Gas (MDEG) Outlet (Class C)

(1) Medical Device, Equipment and Gas (MDEG) Outlets may sell:

(a) Nonprescription drugs;

(b) Specific drugs and materials that require the order or prescription of a practitioner:

(A) USP Oxygen,

(B) USP Sodium Chloride Irrigation,

(C) USP Sodium Chloride Injection,

(D) Sterile water for irrigation,

(E) Urological catheters, and

(F) Respiratory devices

(2) Medicinal Gas Drug Outlets shall distribute medicinal Nitrous Oxide only to practitioners or institutional drug outlets.

(3) Record keeping: All records of receipt and distribution of medical devices, equipment, and gas must be maintained for a minimum of three years and must be readily retrievable.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: PB 1-1992, f. & cert. ef. 1-31-92; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2002, f. & cert. ef. 1-8-02

BOARD OF PHARMACY

DIVISION 41
OPERATION OF PHARMACIES
(AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

855-041-0005 [Renumbered to **855-041-1080]**

855-041-0010 [Renumbered to **855-041-1085]**

855-041-0015 [Renumbered to **855-041-1090]**

855-041-0016 [Renumbered to **855-041-1170]**

855-041-0017 [Renumbered to **855-041-1095]**

855-041-0020 [Renumbered to **855-041-1010]**

855-041-0025 [Renumbered to **855-041-1015]**

855-041-0026 [Renumbered to **855-041-1020]**

855-041-0035 [Renumbered to **855-041-2100]**

855-041-0036 [Renumbered to **855-041-1025]**

855-041-0037 [Renumbered to **855-041-1030]**

855-041-0040 [Renumbered to **855-041-1035]**

855-041-0055 [Renumbered to **855-041-1145]**

855-041-0056 [Renumbered to **855-041-1135]**

855-041-0057 [Renumbered to **855-041-1140]**

855-041-0060 [Renumbered to **855-041-1040]**

855-041-0061 [Renumbered to **855-041-1110]**

855-041-0065 [Renumbered to **855-041-1105,1120,1125,1130]**

855-041-0075 [Renumbered to **855-041-2115]**

855-041-0080 [Renumbered to **855-041-1045]**

855-041-0086 [Renumbered to **855-041-1115]**

855-041-0095 [Renumbered to **855-041-1050]**

855-041-0103 [Renumbered to **855-041-1055]**

855-041-0105 [Renumbered to **855-041-5005]**

855-041-0115 [Renumbered to **855-041-5015]**

855-041-0135 [Renumbered to **855-041-6800]**

855-041-0140 [Renumbered to **855-041-6840]**

855-041-0145 [Renumbered to **855-041-7050]**

855-041-0160 [Renumbered to **855-041-7060]**

855-041-0162 [Renumbered to **855-041-7070]**

855-041-0164 [Renumbered to **855-041-7070]**

855-041-0165 [Renumbered to **855-041-8050]**

855-041-0170 [Renumbered to **855-043-0600]**

855-041-0173 [Renumbered to **855-043-0610]**

855-041-0175 [Renumbered to **855-043-0620]**

855-041-0177 [Renumbered to **855-043-0630]**

855-041-0300 [Renumbered to **855-041-1060]**

855-041-0350 [Renumbered to **855-041-4025]**

855-041-0355 [Renumbered to **855-041-4035]**

855-041-0360 [Renumbered to **855-041-4045]**

855-041-0365 [Renumbered to **855-041-4055]**

855-041-0600 [Renumbered to **855-041-4100]**

855-041-0610 [Renumbered to **855-041-4110]**

855-041-0620 [Renumbered to **855-041-4120]**

855-041-0645 [Renumbered to **855-041-4200]**

General

855-041-1001
Definitions

(1) “Biological product” means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(2) “Biosimilar product” means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).

(3) “Interchangeable” means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).

(4) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

Stat. Auth.: ORS 689.205 & 2013 OL Ch 342
Stats. Implemented: ORS 689.155 & 2013 OL Ch 342
Hist.: BP 2-2014, f. & cert. ef. 1-24-14

855-041-1010
Personnel (Both Retail and Institutional Drug Outlets)

(1) Each pharmacy must have one pharmacist-in-charge employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.

(2) The pharmacy must ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in conformance with the keeping and inventory requirements of federal law and board rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.305
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1986, f. & ef. 12-8-86; PB 10-1987, f. & ef. 12-8-87; PB 9-1989, f. & cert. ef. 7-20-89; PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; BP 1-2001, f. & cert. ef. 3-5-01; BP 2-2008, f. & cert. ef. 2-20-08; Renumbered from 855-041-0020, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1015
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; Renumbered from 855-041-0025, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1020
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 ensure 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- 2100.
(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- 6310, 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 475.035 & 689.205
Stats. Implemented: ORS 689.205
Hist.: 1PB 5-1982, f. & ef. 8-6-82; PB 1-1987, f. & ef. 2-3-87; Renumbered from 855-041-0026, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1025
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1990, f. & cert. ef. 1-23-90; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); Renumbered from 855-041-0036, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1030
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) The outlet shall notify the Board in the event of a significant drug loss or violation related to drug theft within one (1) business day.

(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 be sent to the Board.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented: ORS 689.155
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); Renumbered from 855-041-0037, BP 7-2012, f. & cert. ef. 12-17-12; BP 2-2014, f. & cert. ef. 1-24-14

855-041-1035
Minimum Equipment Requirements (Both Retail and Institutional Drug Outlets)

The minimum equipment requirement to open and operate a retail drug outlet and institutional drug outlet in the state of Oregon shall consist of not less than the following:

(1) The most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(2) Current and properly filed Oregon Revised Statutes, Chapters 689, and 475; current and properly filed Oregon Administrative Rules, chapter 855; and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in house or other readily retrievable means.

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

(4) Suitable refrigeration.

(5) A sink with running hot and cold water.

(6) Equipment and supplies appropriate to and based on the standards of practice for the setting as determined by the Pharmacy and Pharmacist-in-Charge.

(7) Failure to have and use equipment necessary to your practice setting constitutes unprofessional conduct for purposes of ORS 689.405(1)(a).

(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions. Exceptions to the above list may be approved by the Board of Pharmacy.

Stat. Auth.:ORS 689.205 & 689.508
Stats. Implemented: ORS 689.205 & 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; 1PB 4-1986, f. & ef. 12-8-86; PB 8-1987, f. & ef. 9-30-87; PB 12-1989, f. & cert. ef. 8-11-89; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; BP 3-2005, f. & cert. ef. 4-14-05); Renumbered from 855-041-0040, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1036
Proper Storage of Drugs

(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer's published or USP guidelines.

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

(2) A pharmacy must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only; and

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan; and

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.

(3) Vaccine Drug Storage:

(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;

(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and

(E) Must adhere to a written quality assurance process to avoid temperature excursions.

Stat. Auth.: ORS 689.205, 689.325
Stats. Implemented: ORS 689.155
Hist.: BP 3-2015, f. 7-1-15, cert. ef. 1-1-16

855-041-1040
Drug Outlet Procedures

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;
(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;

(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

(5) Ensuring the delivery of each completed prescription to the correct party;

(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;

(7) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties and;

(8) Establishing and maintaining a Continuous Quality Assurance Program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; BP 3-2005, f. & cert. ef. 4-14-05; BP 2-2008, f. & cert. ef. 2-20-08; Renumbered from 855-041-0060, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1045
Returned Drugs and Devices

(1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

(2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been removed from the pharmacy only if;

(a) The drugs or devices are accepted for destruction or disposal and;

(b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or device recall; or

(c) After consultation, a pharmacist determines that, in the pharmacist's professional judgment, harm could result to the public or a patient if the drugs or devices were not accepted for return.

(3) Not withstanding section 2 of this rule, drugs or devices previously dispensed or distributed may be returned and redispensed or redistributed provided all the following conditions are met:

(a) The drug is in an unopened, tamper-evident unit;

(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;

(c) The drug or device has not been adulterated or misbranded and has been stored under conditions meeting United States Pharmacopeia standards.

(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; PB 5-1989, f. & cert. ef. 1-30-89; PB 8-1990, f. & cert. ef. 12-5-90; BP 2-2006, f. & cert. ef. 6-9-06); Renumbered from 855-041-0080, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1050
Pharmacy Depots

(1) Except when delivering directly to a patient, licensed pharmacists may not participate in the transfer of completed prescription medication containers to or from any location that is not a licensed pharmacy, unless the transfer occurs to:

(a) The office of the patient's health care practitioner; or

(b) The location of the patient; or

(A) Patient's primary residence; or

(B) Alternate residence designated by the patient; or

(C) Patient's workplace; or

(c) The hospital or medical care facility in which a patient is receiving care.

(2) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12; BP 1-2012, f. 4-26-12, cert. ef. 5-1-12; Renumbered from 855-041-0095, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1055
Confidentiality

(1) No licensee or registrant of the Board who obtains any patient information shall disclose that information to a third party without the consent of the patient.

(2) Section (1) of this rule does not apply to:

(a) Any disclosure made to the Board;

(b) Any disclosure made to a practitioner or to another pharmacist when the pharmacist reasonably believes that disclosing such information is necessary to protect the patient's health or well being; or
(c) To a third party when disclosure is otherwise authorized or required by law.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented:
Hist.: PB 5-1992, f. & cert. ef. 10-23-92; Renumbered from 855-041-0103, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1060
Non-Resident Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes, but is not limited to: Retail, Institutional, Remote Processing, Central Fill, and Drugless/Consulting Drug Outlets.

(2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state shall be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident pharmacy shall be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) Every out-of-state non-resident pharmacy shall designate an Oregon licensed Pharmacist-in-Charge (PIC), who shall be responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally present in the pharmacy for a minimum of 20 hours per week;

(c) Complete the annual non-resident PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the Board.

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.

(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the Board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy's state of residence and is responsible for the following:

(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

(b) Responding to Board correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the Board within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155 & 689.225
Hist.: PB 1-1994, f. & cert. ef. 2-2-94; BP 2-2008, f. & cert. ef. 2-20-08; Renumbered from 855-041-0300, BP 7-2012, f. & cert. ef. 12-17-12; BP 4-2015, f. & cert. ef. 7-1-15

855-041-1080
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 Division 110 of this Chapter 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) A change of ownership shall be reported to the Board within 15 days of the occurrence.

(15) No pharmacy shall be operated until a certificate of registration has been issued to the pharmacy by the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.155
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; Renumbered from 855-041-0005, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1085
Change of Location of a Pharmacy (Both Retail and Institutional Drug Outlets)

(1) A change of location of a pharmacy requires the approval of the Board and a new certificate of registration.

(2) Application for approval to relocate shall be on a form provided by the Board and shall be accompanied by fees and a floor plan drawn to scale.

(3) A certificate of registration will be issued upon Board approval of the application.

(4) Following Board approval, a change of location, shall be reported to the Board within 15 days of the occurrence.

(5) No pharmacy shall be operated until a certificate of registration has been issued to the pharmacy by the Board.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 5-1990, f. & cert. ef. 4-12-90; PB 1-1994, f. & cert. ef. 2-2-94; Renumbered to 855-041-0010, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1090
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.

(2) Any closure of a pharmacy shall be reported to the Board within 15 days and include notification of the disposition of controlled substances, dangerous, legend, and restricted drugs.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.205
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; Renumbered from 855-041-0015, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1095
Pharmacy Advertising

No person shall advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the Board pursuant to ORS 689.305.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented:
Hist.: PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); Renumbered from 855-041-0017, BP 7-2012, f. & cert. ef. 12-17-12

Prescriptions

855-041-1105
Requirements for Prescriptions

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(2) Each pharmacy must document the following information:

(a) The name of the patient for whom or the owner of the animal and the species of the animal for which the drug is dispensed;

(b) The full name and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner or other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

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

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

(e) The date of filling, and the total number of refills authorized by the prescribing practitioner.

(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent shall clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions shall not be default values on the prescription.

(4) A pharmacy or pharmacist filling a prescription or order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

(d) The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and

(e) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three (3) years.

(5) 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 & 2013 OL Ch. 342
Stats. Implemented: ORS 689.505, 689.515 & 2013 OL Ch. 342
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; 1PB 1-1986, f. & ef. 6-5-86; PB 8-1987, f. & ef. 9-30-87; PB 10-1989, f. & cert. ef. 7-20-89; PB 1-1991, f. & cert. ef. 1-24-91; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 3-1997(Temp), f. & cert. ef. 11-12-97; BP 1-1998(Temp), f. & cert. ef. 1-27-98 thru 5-4-98; BP 2-1998, f. & cert. ef. 3-23-98; BP 2-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 2-2000, f. & cert. ef. 2-16-00; BP 3-2000, f. & cert. ef. 2-16-00; BP 6-2000, f. & cert. ef. 6-29-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 12-2010, f. & cert. ef. 12-23-10; Renumbered from 855-041-0065, BP 7-2012, f. & cert. ef. 12-17-12; BP 2-2014, f. & cert. ef. 1-24-14

855-041-1110
Tamper-resistant Prescription

When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" shall have the meaning as defined in OAR 855-006-0015.

Stat. Auth.: 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2007(Temp), f. & cert. ef. 8-27-07 thru 2-18-08; BP 1-2008, f. & cert. ef. 2-5-08); Renumbered from 855-041-0061, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1115
Verification of Prescription Authenticity

Alteration of a written prescription, other than by a pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 2-2008, f. & cert. ef. 2-20-08; Renumbered from 855-041-0086, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1120
Prescription Refills

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III and IV are limited to five refills or six months from date of issue, whichever comes first.

(2) If the practitioner is not available and in the professional judgment of the pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a

sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner shall be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include.;

(a) The identity of the responsible pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each medication is required.

(6) Auto-Refill Programs. A retail pharmacy may only use a program that automatically refills non-controlled prescriptions that have existing refills available and are consistent with the patient's current medication therapy when the following conditions are met:

(a) Authorization for each prescription refill by a patient or patient's agent is received before the pharmacy begins the filling process;

(b) The prescription is not a controlled substance; and

(c) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient's agent.

(7) An automated reminder cannot be used to generate a prescription refill unless the patient or patient's agent provides authorization for each individual prescription refill. The content of each reminder must include:

(a) Drug name and strength; and

(b) Date of last fill.

(8) Pick-up notification to a patient or patient's agent may only be generated upon full completion of the prescription refill.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.505 & 689.515
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; 1PB 1-1986, f. & ef. 6-5-86; PB 8-1987, f. & ef. 9-30-87; PB 10-1989, f. & cert. ef. 7-20-89; PB 1-1991, f. & cert. ef. 1-24-91; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 3-1997(Temp), f. & cert. ef. 11-12-97; BP 1-1998(Temp), f. & cert. ef. 1-27-98 thru 5-4-98; BP 2-1998, f. & cert. ef. 3-23-98; BP 2-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 2-2000, f. & cert. ef. 2-16-00; BP 3-2000, f. & cert. ef. 2-16-00; BP 6-2000, f. & cert. ef. 6-29-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 12-2010, f. & cert. ef. 12-23-10; Renumbered from 855-041-0065, BP 7-2012, f. & cert. ef. 12-17-12; BP 12-2014, f. 12-30-14, cert. ef. 1-1-16; BP 9-2015, f. 12-23-15, cert. ef. 7-1-16

855-041-1125
Prescription Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.

(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.

(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed one year.

(3) The prescription shall not be refilled out of context with the approximate dosage schedule unless specifically authorized by the prescriber.

(4) 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.505 & 689.515
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; 1PB 1-1986, f. & ef. 6-5-86; PB 8-1987, f. & ef. 9-30-87; PB 10-1989, f. & cert. ef. 7-20-89; PB 1-1991, f. & cert. ef. 1-24-91; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 3-1997(Temp), f. & cert. ef. 11-12-97; BP 1-1998(Temp), f. & cert. ef. 1-27-98 thru 5-4-98; BP 2-1998, f. & cert. ef. 3-23-98; BP 2-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 2-2000, f. & cert. ef. 2-16-00; BP 3-2000, f. & cert. ef. 2-16-00; BP 6-2000, f. & cert. ef. 6-29-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 12-2010, f. & cert. ef. 12-23-10; Renumbered from 855-041-0065, BP 7-2012, f. & cert. ef. 12-17-12

Labeling

855-041-1130
Prescription Labeling

(1) Prescriptions must be labeled with the following information:

(a) Name, address and telephone number of the pharmacy;

(b) Date;

(c) Identifying number;

(d) Name of patient;

(e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier 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 judgment, 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) 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.

(l) 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 & 689.515
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1984, f. & ef. 4-16-84; 1PB 1-1986, f. & ef. 6-5-86; PB 8-1987, f. & ef. 9-30-87; PB 10-1989, f. & cert. ef. 7-20-89; PB 1-1991, f. & cert. ef. 1-24-91; PB 4-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 3-1997(Temp), f. & cert. ef. 11-12-97; BP 1-1998(Temp), f. & cert. ef. 1-27-98 thru 5-4-98; BP 2-1998, f. & cert. ef. 3-23-98; BP 2-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 2-2000, f. & cert. ef. 2-16-00; BP 3-2000, f. & cert. ef. 2-16-00; BP 6-2000, f. & cert. ef. 6-29-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 12-2010, f. & cert. ef. 12-23-10; Renumbered from 855-041-0065, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1135
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); Renumbered from 855-041-0056, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1140
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.

(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: PB 1-1989, f. & cert. ef. 1-3-89; Renumbered from 855-041-0057, BP 7-2012, f. & cert. ef. 12-17-12; BP 8-2013, f. & cert. ef. 9-25-13

Dispensing

855-041-1145
New Containers

In filling the original prescriptions, nothing but new containers may be used. A patient's original container may be refilled if clean and the label is legible and up-to-date. The container shall comply with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations adopted thereunder. It must also conform with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling. [Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80); Renumbered from 855-041-0055, BP 7-2012, f. & cert. ef. 12-17-12

Records

855-041-1160
Prescription Records and Retention

(1) Definitions. The following definitions apply to this rule:

(a) An "original prescription" is a prescription maintained in the same physical manner in which a pharmacy first receives the prescription. For example, for a prescription received by the pharmacy in writing on a prescription form, the original prescription consists of the original writing on the prescription form. For a prescription received by the pharmacy orally over the telephone, the original consists of the writing or electronic record that reflects receipt of the oral prescription.

(b) "Filing" and "file" mean the storage of the original prescription in such a manner that the original prescription is safeguarded and readily retrievable.

(2) Every pharmacy and pharmacist-in-charge of a pharmacy must ensure that original prescriptions are properly filed in compliance with this rule.

(3) All original prescriptions shall be filed for a minimum of three years from the date of first dispensing and shall at all times be open for inspection by the prescriber, and the Board of Pharmacy or its duly authorized agent.

(4) After 120 days, the paper prescription may be destroyed and filed in an electronic form if:

(a) The electronic form shows the exact and legible image of the original prescription;

(b) Notes of clarifications of and changes to the prescription are directly associated with the electronic form of the prescriptions; and

(c) The prescription is not for a controlled substance.

(5) This rule is not intended to alter or supersede the recordkeeping requirements of any other federal or Oregon statute or rule, including but not limited to ORS 689.508, OAR 855-041-1120, and rules related to records for prescriptions for controlled substances.

(6) Unless specified otherwise, all records and documentation required by OAR 855 Division 041 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; BP 3-2005, f. & cert. ef. 4-14-05; BP 2-2008, f. & cert. ef. 2-20-08; Renumbered from 855-041-0060, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1165
Patient Medical Record

(1) A patient record system shall be maintained by pharmacies for all patients for whom prescription drug orders are dispensed, except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs. The patient record system shall provide for readily retrievable information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

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

(b) Address and telephone number of the patient;

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

(d) Patient's gender;

(e) Chronic medical conditions;

(f) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(g) Known allergies, drug reactions, and drug idiosyncrasies; and

(h) If deemed relevant in the pharmacist's professional judgment:

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

(B) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.508
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; BP 3-2005, f. & cert. ef. 4-14-05; BP 2-2008, f. & cert. ef. 2-20-08; Renumbered from 855-041-0060, BP 7-2012, f. & cert. ef. 12-17-12

855-041-1170
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

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

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist’s ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Immunization;

(C) Counseling;

(D) Verification of the accuracy of a prescription; and

(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.

(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.
(5) Incenting or inducing the transfer of a prescription absent professional rationale.

Stat. Auth: ORS 689.151, 689.155(2), 689.205, 689.225(4)
Stat. Implemented: ORS 689.155
Hist.: BP 2-2012, f. & cert. ef 6-12-12; Renumbered from 855-041-0016, BP 7-2012, f. & cert. ef. 12-17-12

855-041-2100
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- 6310, 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 689.205
Stats. Implemented: ORS 689.205
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; Renumbered from 855-041-0035, BP 7-2012, f. & cert. ef. 12-17-12

855-041-2115
Transfer of Prescription Information Between Pharmacies

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

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

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1982, f. & ef. 3-8-82; 1PB 1-1986, f. & ef. 6-5-86; PB 2-1990, f. & cert. ef. 2-9-90; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); BP 2-1998, f. & cert. ef. 3-23-98; BP 6-2000, f. & cert. ef. 6-29-00; Renumbered from 855-041-0075, BP 7-2012, f. & cert. ef. 12-17-12

Distribution of Emergency Medication

855-041-2300
Purpose and Scope

The purpose of OAR 855-041-2300 through 855-041-2330 is to define the procedures for distributing emergency medication to certain authorized individuals for the use in emergency health circumstances. The authorized person is someone who has been trained under the guidelines set forth in 333-055-0110.

Stat. Auth: ORS 689.205& 2013 OL Ch. 340
Stats. Implemented: ORS 689.155 & 2013 OL Ch. 34
Hist.: BP 6-2013(Temp), f. 9-23-13, cert. ef. 9-24-13 thru 3-23-14; BP 2-2014, f. & cert. ef. 1-24-14

855-041-2310
Definitions

The following words and terms, when used in OAR 855-041-2300 through 855-041-2330 shall have the following meanings, unless the context clearly indicates otherwise.

(1) “Allergic reaction” means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.

(2) “Authorization to Obtain Epinephrine” means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.

(3) “Authorization to Obtain Naloxone” means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of naloxone to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of naloxone orders filled to date.

(4) “Opiate” means a narcotic drug that contains: opium, any chemical derivative of opium, or any synthetic or semi-synthetic drug with opium-like effects.

(5) “Opiate overdose” means a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function, and the impairment of vital functions as a result of ingesting opiates in any amount larger than can be physically tolerated.

(6) “Statement of Completion” means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee’s name and address, the name of the authorized trainer and the date that the training was completed.

(7) “Supervising Professional” means a physician or nurse practitioner licensed to practice in this state who has prescription writing authority.

(8) “Trainee” means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.

(9) “Trainer” means an individual conducting the formal training as directed by the supervising professional and in accordance with the protocols and criteria established by the Oregon Health Authority, Public Health Division.

Stat. Auth: ORS 689.205 & 2013 OL Ch. 340
Stats. Implemented: ORS 689.155 & 2013 OL Ch. 340
Hist.: BP 6-2013(Temp), f. 9-23-13, cert. ef. 9-24-13 thru 3-23-14; BP 2-2014, f. & cert. ef. 1-24-14

855-041-2320
Epinephrine

(1) A pharmacist may fill an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

(2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Epinephrine.

(3)(a) Distribution of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manner:

(b) A trainee may obtain epinephrine upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy which:

(A) A pharmacist may generate a prescription for, and dispense an emergency supply of epinephrine for not more than one (1) child and one (1) adult in an automatic injection device, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.

(B) The pharmacist who generates the hardcopy prescription for epinephrine in this manner shall reduce the prescription to writing, and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the pharmacist generates the epinephrine prescription, the pharmacist shall write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate, the date and the number of doses dispensed, and return the certificate to the trainee.

(4) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.

(a) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three

(3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.

(b) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.

Stat. Auth: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 6-2013(Temp), f. 9-23-13, cert. ef. 9-24-13 thru 3-23-14; BP 2-2014, f. & cert. ef. 1-24-14

855-041-2330
Naloxone

(1) A Pharmacy may fill orders for unit-of-use naloxone to be used by trainees for opiate overdose emergencies. Individuals must successfully complete a training program approved by the Oregon Health

Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Naloxone.

(2) Distribution of naloxone from a pharmacy to be used for opiate overdose emergencies may occur in the following ways:

(a) A supervising professional may obtain a supply of naloxone for a program pursuant to a request by the supervising professional and a pharmacy sale by invoice. The pharmacy shall keep the invoice on record for three (3) years.

(b) A trainee may obtain naloxone upon presentation of the Statement of Completion and Authorization to Obtain Naloxone certificate to a pharmacy which:

(A) A pharmacist may generate a prescription for, and dispense up to two (2) unit-of-use doses of naloxone as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Naloxone certificate.

(B) The pharmacist who generates the hardcopy prescription for naloxone in this manner shall reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the pharmacist generates the naloxone prescription, the pharmacist shall write in the appropriate space provided on the Authorization to Obtain Naloxone certificate the date and the number of doses dispensed, and return the certificate to the trainee.

(3) The Statement of Completion and Authorization to Obtain Naloxone certificate may be used to obtain naloxone up to six (6) times within three (3) years from the date of the initial training.

(a) Both the Statement of Completion and the Authorization to Obtain Naloxone certificate expire three

(3) years from the date of the trainee's last Oregon Health Authority, Public Health Division approved naloxone training.

(b) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Naloxone, with a valid duration of three (3) years.

(4) The naloxone container must be labeled with the following information:

(a) A statement that the naloxone is intended for use in the Oregon Opiate Overdose Treatment program;

(b) Trainees name; and

(c) Trainer; or

(d) Supervising Professional.

Stat. Auth: ORS 689.205 & 2013 OL Ch. 340
Stats. Implemented: ORS 689.155 & 2013 OL Ch. 340
Hist.: BP 6-2013(Temp), f. 9-23-13, cert. ef. 9-24-13 thru 3-23-14; BP 2-2014, f. & cert. ef. 1-24-14

855-041-2340
Pharmacist Prescribing of Naloxone

(1) A pharmacist educated in opiate overdose and naloxone rescue may prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone to an individual who:

(a) Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medical supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(2) The pharmacy providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

(a) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and

(b) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
Hist.: BP 5-2016(Temp), f. & cert. ef. 9-7-16 thru 3-5-17; BP 6-2016, f. & cert. ef. 12-14-16

Central Fill Drug Outlets, Remote Processing Drug Outlets and Consulting or Drugless Pharmacies

855-041-3000
Purpose and Scope

(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.

(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.

(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.

(4) The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety must be submitted to the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

Central Fill Drug Outlets

855-041-3005
Purpose and Scope

The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy. Any facility established for the purpose of filling drug orders on behalf of an Oregon pharmacy shall be licensed as a retail or institutional drug outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant must

submit to the Board for approval policies and procedures and a description of how using central fill will improve patient safety and redirect a pharmacist at a primary pharmacy from a distributive task to a cognitive task.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3010
Definitions

The following words and terms, when used in OAR 855-041-3005 through 855-041-3045 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the OAR chapter 855, division 006.

(1) “Central Fill Pharmacy” means an Oregon licensed pharmacy that provides centralized prescription filling for both initial or prescription refills on behalf of a primary pharmacy.

(2) “Primary Pharmacy” means a pharmacy located and licensed in Oregon that receives a patient’s or a prescribing practitioner’s request to fill a prescription, dispenses the prescription directly to the patient or patient’s agent, or the pharmacy delivers the drug to the patient’s agent for administration. The primary pharmacy maintains ownership of the prescription.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3015
General Requirements

An Oregon licensed pharmacy may outsource prescription drug filling to a central fill pharmacy provided that both pharmacies:

(1) Have the same owner; or

(2) Have a written shared pharmacy services contract or agreement that specifies:

(a) The services to be provided by each pharmacy;

(b) The responsibilities of each pharmacy; and

(c) The accountabilities of each pharmacy.

(3) Maintain a separate Oregon pharmacy license for each location involved in providing prescription drugs and services to Oregon patients;

(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to fill a prescription drug order;

(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3020;

(6) Ensure that each prescription has been properly processed and filled and that counseling has been provided to the patient;

(7) Designate a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing boards;

(8) Conduct an annual review of the written policies and procedures and document such review;

(9) Comply with all applicable federal and state laws and rules;

(10) Direct all patient communication to the primary pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3020
Policies and Procedures

(1) In addition to the requirements of OAR 855-041-1040, the central fill pharmacy and the primary pharmacy is each accountable for establishing, maintaining, and enforcing its written policies and procedures manual. The policies and procedures manual must include, but need not be limited to the following:

(a) The responsibilities of each pharmacy;

(b) The policies and procedures that protect confidentiality and ensure integrity of patient information;

(c) Compliance with all applicable federal and state laws and rules;

(d) Cancelation of a filled prescription after the prescription is filled by the primary pharmacy;

(e) Records sufficient to identify by name, initials or unique identification code, the identify and specific activities of each pharmacist or technician who performed any centralized filling function, and the pharmacy where each activity was performed;

(f) The mechanism for tracking the prescription drug order during each step in the filling and dispensing process;

(g) Pharmacist completion of a Drug Utilization Review (DUR) on each prescription;

(h) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities, to improve patient care, and to resolve identified problems;

(i) Documentation of any errors or irregularities identified by the quality improvement program;

(2) This manual shall be maintained at both the central fill and primary pharmacy and must be made available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3025
Labeling

(1) The label affixed to the prescription container filled by a central fill pharmacy on behalf of the primary pharmacy shall:

(a) Include all information required by OAR 855-041-1130 and OAR 855-041-1140;

(b) Comply with all labeling requirements identifying only the primary pharmacy.

(2) If the Central Pharmacy dispenses the completed prescription to the patient, the label must also comply with retail labeling requirements in OAR 855-041-1130 through 855-041-1140.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3030
Records

(1) The recordkeeping requirements in OAR 855-041-3005 through 855-041-3045 are in addition to the requirements of other recordkeeping rules of the Board.

(2) Each recordkeeping system must include quality improvement program documentation.

(3) Unless otherwise specified, all records and documentation required by OAR 855-041-3005 through 855-041-3045 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be kept in hard copy, electronic copy, or a combination of the two.

(4) Each pharmacy must be able to produce an audit trail which identifies each prescription process in their pharmacy.

(5) The primary pharmacy shall maintain the original prescription for a period of three years from the date the prescription was filled.

(6) The primary pharmacy must maintain records that:

(a) Identify by prescription or drug order, the name or unique identification code of the pharmacist who performed the drug utilization review. Identify by prescription drug order the pharmacist or technician that transmitted the prescription drug order to the central fill pharmacy. These records may be maintained separately by each pharmacy and pharmacist or technician or in a common electronic file, as long as the data processing system is capable of producing a printout that lists each function performed by each pharmacy and pharmacist or technician, and identifies the pharmacist or technician who performed each function;

(b) Document the date the filled prescription was received from the central fill pharmacy and the name of the person accepting delivery.

(7) The central fill pharmacy must maintain records that:

(a) List the name, address, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized prescription filling; and

(A) Document verification of each license and registration; and

(B) Document the name of the individual responsible for verification of licensure and registration status.

(b) Track the prescription drug order during each step in the filling process and identify the name, initials, or unique identification code and specific activity of each pharmacist or pharmacy technician who performed any portion of the process including transmission, filling, dispensing and delivery of information.

(A) The date the prescription was received by the central fill pharmacy;

(B) The name and address where the filled prescription was shipped;

(C) The method of delivery (e.g., private, common, or contract carrier).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3035
Delivery of Medications

(1) A central fill pharmacy may deliver or mail medications to the primary pharmacy or patient in compliance with OAR 855-041-1050.

(2) A central fill pharmacy must comply with all federal and state requirements when using private, common or contract carriers to transport filled prescriptions for delivery. When a central fill pharmacy contracts with private, common or contract carriers to transport filled prescriptions the central fill pharmacy is responsible for reporting any in-transit loss upon detection by use of DEA Form 106.

(3) A central fill pharmacy must maintain and use adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of packaging material and devices to ensure that the drug is maintained at the temperature range required to maintain the integrity of the medication throughout the delivery process.

(4) Filled prescriptions must be shipped in containers that are sealed in a manner that shows evidence of opening or tampering.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3040
Filled Prescriptions

(1) Any filled prescription that has not been picked up, may be put into the primary pharmacy's inventory. Each pharmacy is responsible for documenting any such transfer of a drug.

(2) A prescription for a controlled substance may be filled by a central fill pharmacy when permitted by law, consistent with federal requirements set forth at 21 C.F.R. ¦ 1300 et seq;

(3) The pharmacy that fills the prescription and the pharmacy to which the filled prescription is provided for dispensing to the patient shall each be responsible for ensuring the prescription has been properly filled.

(4) A primary pharmacy will notify the patient of the possible use of a central fill pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3045
Prohibited Practices

(1) A primary pharmacy may not use the services of a central fill pharmacy that is not registered with the Board.

(2) A central fill pharmacy may not fill a prescription on behalf of a primary pharmacy that is not registered with the Board if the laws and rules of Oregon require the primary pharmacy to be registered with the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

Remote Processing Drug Outlets

855-041-3100
Purpose and Scope

The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription drug processing by a pharmacy. Any facility that processes drug orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant must submit to the Board for approval policies and procedures and a description of how using remote processing will improve patient safety.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3105
Definitions

The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in OAR chapter 855, division 006.

(1) “Remote Processing Pharmacy” means an Oregon licensed pharmacy operated under the direction of a pharmacist-in-charge that processes information related to the practice of pharmacy and engages in remote prescription processing, including central processing.

(2) “Remote Processing Functions” may include, but are not limited to, data entry, prospective drug utilization reviews, refill authorizations and interventions. This does not include the filling process.

(3) “Primary Pharmacy” means an instate Oregon licensed pharmacy that receives a patient’s or a prescribing practitioner’s request to fill a prescription or drug order and delivers the drug or device directly to the patient or patient’s agent, and maintains ownership of the prescription or drug order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3110
General Requirements

An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided both pharmacies:

(1) Have the same owner; or

(2) Have a written shared pharmacy services contract or agreement that specifies:

(a) The services to be provided by each pharmacy;

(b) The responsibilities of each pharmacy; and

(c) The accountabilities of each pharmacy.

(3) Maintain a separate Oregon pharmacy license for each location involved in providing services;

(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;

(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;

(6) Ensure that each prescription has been properly processed, filled and counseling has been provided to the patient;

(7) Designate a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the pharmacy's resident state if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;

(8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in which the pharmacy is located;

(9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the pharmacy is located;

(10) Comply with all applicable federal and state laws and rules;

(11) Conduct an annual review of the written policies and procedures and document such review.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3115
Policies and Procedures

(1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and procedures manual. The policies and procedures manual must include, but need not be limited to the following:

(a) The responsibilities of each pharmacy;

(b) The policies and procedures that protect confidentiality and ensure the integrity of patient information;

(c) Compliance with all applicable federal and state laws and rules;

(d) Records sufficient to identify by name, initials, or unique identification code, the identity and the specific activities of each pharmacist or technician who performed any processing function, and the location where each activity was performed;

(e) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and to resolve identified problems; and

(f) Documentation of any errors or irregularities identified by the quality improvement program.

(2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote processing and must be available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3120
Records

(1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the requirements of other recordkeeping rules of the Board.

(2) The remote processing pharmacy must maintain all required records unless these records are maintained in the primary pharmacy.

(3) Both recordkeeping systems must:

(a) List the name, address, telephone number, and all license and registration numbers of each pharmacy involved in remote prescription processing;

(A) Document verification of each license and registration;

(B) Document the name of the individual responsible for verification of licensure and registration status.

(b) Identify by name, initials, or unique identification code the identity and the specific activities of each pharmacist or technician who performed any part of the prescription process;

(c) Include quality improvement program documentation;

(d) Be able to produce an audit trail showing each prescription process.

(4) Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two;

(5) The primary pharmacy shall maintain records that:

(a) Indicate the date the request for processing was transmitted to the remote processing pharmacy; and

(b) Indicate the date the prescription information was received by the primary pharmacy.

(6) The remote processing pharmacy shall maintain records that:

(a) Track the prescription drug order during each step in the order entry process;

(b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist or pharmacy technician who performed any activity related to processing the prescription including receipt, transmission or delivery of information.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3125
Prescription or Drug Order Processing

A prescription or drug order for a controlled substance may be processed by a remote processing pharmacy when permitted by law and consistent with federal rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3130

Prohibited Practices

A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is not registered with the Board, if required by the laws and rules of Oregon to be registered.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

Consulting or Drugless Pharmacies

855-041-3300
Purpose and Scope

The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a single physical location. This location may be an office located in a home or other secure location. Registration is not required if records used or generated by a consulting pharmacist are stored in a location registered by the Board as a retail or institutional drug outlet or if the location is under the control of a practitioner who uses the services of the consulting pharmacist. The consulting pharmacist must be able to provide the Board with documentation of their pharmaceutical care activities. These rules are intended to ensure that a location where a pharmacist is engaged in Independent Pharmacy Practice may safely store records and protected health information. An applicant must submit to the Board for approval policies and procedures and a description of how their consulting or drugless pharmacy will be utilized to improve patient safety.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3305
Definitions

The following words and terms, when used OAR 855-041-3300 through 855-041-3340 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the OAR chapter 855, division 6.

(1) “Consulting or Drugless Pharmacy” means any single physical location where pharmaceutical care services are performed or protected health information may be stored without the storage, possession, or ownership of any drug.

(2) “Consulting Pharmacist” means any pharmacist as defined by OAR chapter 855, division 6 and is described by chapter 855, division 19.

(3) “Independent Pharmacy Practice” means the provision of pharmaceutical services not related to physically handling or dispensing pharmaceuticals drugs or devices. This practice is characterized by the practice of an Oregon licensed pharmacist acting as an independent contractor whether or not directly employed or affiliated with an entity that is licensed by the Board. This service also does not include the provision of pharmaceutical care that is conducted within the physical confines or location of a licensed pharmacy registered with the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3310
Registration

(1) The Consulting Pharmacy shall be registered as a retail or institutional drug outlet and comply with all the requirements of licensure as defined in OAR 855-041-1080 through 855-041-1100.
(2) The location must be available for inspection by the Board.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3315
Personnel

(1) Each pharmacy must have a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;

(2) The pharmacy must comply with all applicable state and federal laws and rules governing the practice of pharmacy and maintain records in compliance with requirements of federal law and Board rules;

(3) A consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon; and

(4) Prospective drug utilization reviews, refill authorizations, interventions and patient counseling not associated with the dispensing of a drug for an Oregon patient must be performed by an Oregon licensed pharmacist.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3320
Confidentiality

(1) Each consulting pharmacy must comply with all applicable federal and state laws and rules regarding confidentiality, integrity and privacy of patient information.

(2) Each consulting pharmacy must ensure that electronic data systems are secure and comply with applicable federal and state laws and rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3325
General Provisions and Minimum Standards

(1) A consulting pharmacy shall:

(a) Maintain appropriate reference materials for drug information according to the scope of consulting services.

(b) Be located in a secure room with a door and suitable lock, and accessible only to persons authorized by the pharmacist-in-charge.
(c) Provide storage sufficient to secure confidential documents and any hardware necessary to access information.

(d) Be constructed in a manner of materials that make the space separate and distinct from the rest of the home or office building, and that protects the records from unauthorized access.

(2) A consulting pharmacy located in a residence must be approved by the Board.

(3) The consulting pharmacist must be able to provide the Board, upon request, with documentation of their pharmaceutical care activities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3330
Security Requirements

(1) All consulting services must occur in a secure environment that includes but is not limited to:

(a) A closed system or other electronic storage device that is password protected;

(b) A secure room or safe that is locked to store records when the pharmacist is not directly monitoring them;

(c) Sufficient encryption for securing confidential documents and any hardware used in accessing authorized patient health information by electronic connection; and

(d) A data processing system that complies with all federal and state laws and rules to ensure compliant security software.

(2) Records stored at a practitioner's office must be kept secure either with other records at the facility or independently in a locked room where only the pharmacist, and physician and their agents have access;

(3) All records must be stored at the approved consulting or drugless pharmacy; and

(4) Any breach in the security of the system or breach of confidentiality must be documented and reported to the Board within seven days.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3335
Policies and Procedures

The consulting pharmacy must maintain a current policy and procedures manual that includes at a minimum:

(1) A policy on protecting confidentiality and integrity of patient information;

(2) An outline of responsibilities and scope of services;

(3) A policy on compliance with federal and state laws and rules;
(4) An operational Quality Assurance Program;

(5) A policy that describes use of computer systems.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

855-041-3340
Records

(1) The recordkeeping and storage requirements in OAR 855-041-3300 through 855-041-3340 are in addition to the requirements of other recordkeeping and storage rules of the Board. Records and documentation may be written, electronic or a combination of the two.

(2) Each recordkeeping system must include quality improvement program documentation;

(3) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety, and welfare. Records must include but need not be limited to:

(a) Patient profiles and records;

(b) A list of current employees and their license numbers;

(A) Verification of each license and registration;

(B) The name of the individual responsible for verification of licensure and registration status.

(c) Copies of all contracts for consulting services and collaborative therapy agreements;

(d) Copies of all consultation reports submitted to practitioners and facilities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 10-2013, f. & cert. ef. 11-6-13

Expedited Partner Therapy

855-041-4000
Purpose

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

855-041-4005
Procedures

(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule shall govern.

(3) An EPT prescription may only be dispensed for a drug that has been determined by the Department of Human Services (DHS) to be appropriately used for EPT.

Prescription

(4) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a hand written or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write “for EPT,” or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an “EPT Prescription,” or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as “John Doe – Partner 1” or by labeling the prescription as “EPT Partner”

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the pharmacist must contact the prescriber or the prescriber’s agent and must record the additional information on the prescription.

(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.

Labeling

(6) The pharmacist must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(7) The pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The pharmacist is not required to obtain an EPT patient’s or partner’s name, address, or demographics; however, the pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

Retail Drug Outlet for Home Dialysis Supplies

855-041-4025
Purpose and Scope

A Retail Drug Outlet for Home Dialysis supplies may provide dialysis solutions under the general supervision and direction of a pharmacist with special training in renal disease and dialysis to end stage renal disease (ESRD) patients who have chosen the option of home dialysis therapy and who have been appropriately trained.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00; Renumbered from 855-041-0350, BP 7-2012, f. & cert. ef. 12-17-12

855-041-4035
Definitions

"Dialysis solutions" means peritoneal dialysis solutions, dialysate solutions, and legend devices including hardware, bloodlines and dialysis tubing and connectors.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00; Renumbered from 855-041-0355, BP 7-2012, f. & cert. ef. 12-17-12

855-041-4045
Drug Delivery and Control

(1) An Oregon licensed pharmacist must be designated as the pharmacist-in-charge who will provide direction and supervision of the operation and staff.

(2) Deliveries of supplies must be made only pursuant to a current prescription order from an authorized prescriber. The prescription order must be maintained on file at the outlet. Supplies will be limited to dialysis solutions as defined in OAR 855-041 — 4035. No other legend medication ordered for the patient may be provided by the outlet.

(3) All patient records must be maintained in a secure area with a locking door. Access to the patient records area is allowed only when a pharmacist is present except in the event of an emergency. In the event of an emergency, any entry by individuals other than the pharmacist must be documented. In the absence of a pharmacist, the door to the patient records area must remain locked at all times.

(4) Copies of all prescriptions must be reviewed by the pharmacist and a complete set of prescription records for all patients serviced by the outlet must be maintained in the patient records area for a minimum of three years.

(5) A minimum of two current reference books that are specific and relevant to dialysis therapy must be maintained in the outlet to assist in the appropriate delivery of care to patients. Other reference material and equipment must be maintained to be consistent with the scope of services provided by the outlet.

(6) A current copy of Oregon Revised Statutes, Chapter 689, a current copy of Oregon Administrative Rules, chapter 855, and a minimum of three years of the Oregon Board of Pharmacy quarterly newsletters must be maintained in a loose leaf binder or other readily retrievable means.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00; Renumbered from 855-041-0360, BP 7-2012, f. & cert. ef. 12-17-12

855-041-4055
Duties of the Pharmacist

(1) The pharmacist-in-charge must review, at least weekly, the drug outlet operation and perform, at least monthly, quality assurance audits that include the review of prescription orders prior to delivery for accuracy and completeness, and the review of the assembled order with the prescription order prior to delivery for accuracy and completeness.

(2) The pharmacist-in-charge is responsible for the following on an ongoing basis:

(a) Ensure compliance of dialysis distribution operation to all applicable federal and state pharmacy laws and rules;

(b) Ensure valid prescriptions are received for all patient orders by performing periodic assessments of prescription files;

(c) Perform periodic assessments of distribution processes and procedures to ensure quality and compliance;

(d) Provide pharmaceutical care by reviewing all patient profiles and performing drug therapy assessments on those identified as abnormal;

(e) Provide pharmaceutical care by responding on a toll free telephone access to questions received from any patient or health care provider;

(f) Maintain, update and train personnel on policies and procedures specific to home dialysis patient deliveries and pharmacy requirements;

(g) Prepare educational materials for staff members of dialysis clinics as requested;

(h) Prepare and maintain on file monthly reports of activities performed;

(i) Ensure security of the patient record area; and

(j) Maintain a policy and procedure manual for the Drug Outlet operation that must include written protocols for the product delivery system, methods for supervising deliveries to patients, and a quality assurance program with which to monitor the qualifications, training and performance of personnel.
(3) The pharmacist-in-charge must perform an annual inspection of the outlet on a form provided by the Board, and must provide a copy of this inspection to the Board upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 8-2000, f. & cert. ef. 6-29-00; Renumbered from 855-041-0365, BP 7-2012, f. & cert. ef. 12-17-12

Remote Dispensing

855-041-4100
Definitions

(1) "Automated Pharmacy System" (APS) means a mechanical system that performs operations or activities, including but not limited to, those related to the storage, packaging, dispensing, or distribution of medications, but not including compounding or administration, and that collects, controls, and maintains all transaction information.

(2) "Remote Dispensing Facility" (RDF) means a facility where drugs are prepared for administration and where requisite pharmacist supervision is provided remotely as approved by the Board.

(3) "Remote Dispensing Machine" (RDM) means a component of an Automated Pharmacy System that contains prepackaged drugs for dispensing.

(4) "Responsible Pharmacy" means the licensed pharmacy that is responsible for the APS, and RDM.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; BP 9-2010(Temp), f. & cert. ef. 7-9-10 thru 12-24-10; Administrative correction 1-25-11; BP 3-2011, f. & cert. ef. 4-18-11; Renumbered from 855-041-0600, BP 7-2012, f. & cert. ef. 12-17-12

855-041-4110
Duties and Responsibilities of the Pharmacist-in-Charge.

Each RDM must be under the supervision of the Pharmacist-in-Charge of the Responsible Pharmacy. The Pharmacist-in-Charge must:

(1) Develop written policies and procedures prior to installation of the RDM that:

(a) Ensure safety, accuracy, security, and patient confidentiality;

(b) Define access to the RDM and to medications contained within or associated with the RDM, including but not limited to policies that assign, discontinue, or change access to the RDM and medications.

(c) Ensure that access to the medications complies with state and federal laws and regulations.

(2) Obtain written approval by the Board prior to installing any RDM.

(3) Train all personnel who will access the APS (including the RDM) before being allowed access to the APS. Training must ensure the competence and ability of all personnel who operate any component of the APS. Documentation of original training and continuing education must be kept both in the pharmacy and at the site of the RDM, and readily available for inspection by the Board.

(4) Ensure that the RDM is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record-keeping and security safeguards.

(5) Implement an ongoing quality assurance program that monitors performance of the APS, including the RDM, and the personnel who access it.

(6) Notify the Board within 15 days of removal or closure of the RDM and the disposition of drugs contained in the RDM before it was removed or closed.

(7) Ensure that the RDM is stocked accurately and in accordance with established, written policies and procedures. A pharmacist must check the accuracy of the product supplied for stocking the machine.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.205
Hist.: BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; Renumbered from 855-041-0610, BP 7-2012, f. & cert. ef. 12-17-12

855-041-4120
Drug Delivery and Control

(1) Each RDM must be registered with the Board, under the control of and connected via computer with a Responsible Pharmacy, but not located in a pharmacy. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws and regulations.

(2) The following must be conspicuously displayed at the site of the RDM:

(a) RDM license;

(b) DEA registration if required;

(c) A certified copy of the Responsible Pharmacy license; and

(d) A certified copy of the Pharmacist-In-Charge license.

(3) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained in the pharmacy for review by the board. Such documentation must include, but is not limited to:

(a) Location of RDM(s);

(b) Manufacturer's name and model for each RDM;

(c) Description of how the RDM is used;

(d) Quality assurance procedures to determine continued appropriate use of the automated device; and

(e) Policies and procedures for training of appropriate personnel, system operation, safety, security, accuracy, patient confidentiality, oral counseling by a pharmacist or pharmacist-intern, access, and malfunction.

(4) Policies and procedures addressing the operation of the RDM must be maintained in the pharmacy responsible for the APS and at the location at which the RDM has been installed.

(5) All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the pharmacy for a minimum of three years and must be readily available to the Board. Such records shall include:

(a) Identity of RDM accessed;

(b) Identification of the individual accessing the RDM;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form, and quantity of the drug accessed;

(f) Name of the patient for whom the drug was ordered;

(g) Name of the prescribing practitioner

(h) Such additional information as the pharmacist-in-charge may deem necessary; and

(6) Only an Oregon registered technician or an Oregon licensed pharmacist may have access to the RDM.

(7) Only an Oregon registered technician or an Oregon licensed pharmacist may stock medications in the RDM.

(8) All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws and regulations, including OAR 855-041-1130.

(9) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(10) Oral counseling, as required by OAR 855-019-0230, shall be provided by the pharmacist at the time of dispensing by a two-way audio and video hookup with the Responsible Pharmacy.

(11) The Automated Pharmacy Systems shall provide a mechanism for securing and accounting for wasted, discarded or unused medications in accordance with existing state and federal laws and regulations.

(12) The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist-In-Charge.

(13) A Responsible Pharmacy located outside of Oregon that operates a RDM in Oregon must be currently licensed and in good standing in Oregon. The Pharmacist-In-Charge must also be currently licensed and in good-standing both in Oregon and in the state in which the Responsible Pharmacy is located.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.205
Hist.: BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; Renumbered from 855-041-0620, BP 7-2012, f. & cert. ef. 12-17-12

Remote Distribution Facilities

855-041-4200
Remote Dispensing Facility (RDF)

(1) A pharmacy physically located in Oregon may make written application to operate an RDF.

(2) The Board may approve an application for registration as an RDF which includes the following:

(a) An operation plan;

(b) Policies and Procedures;

(c) A training plan;

(d) A quality assurance plan for ensuring that there is a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems; and

(e) The fee specified in OAR 855-110.
(3) Notwithstanding the definition of “supervision by a pharmacist” in OAR 855-006-0005, supervision in an RDF may be accomplished by a pharmacist via an audio-visual technology from the applying pharmacy.

(4) Notwithstanding rules in this division and in divisions 19 and 25, a Certified Oregon Pharmacy Technician who works in an RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2011, f. & cert. ef. 4-18-11; Renumbered from 855-041-0645, BP 7-2012, f. & cert. ef. 12-17-12; BP 1-2014, f. & cert. ef. 1-3-14; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

Residential Drug Outlets

855-041-5005
Definitions

For purposes of these rules, OAR 855-041-5000 through 855-041-9999 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. For the purpose of this rule, an Institutional Facility is a Residential Drug Outlet.

(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; and

(c) For the purpose of this rule, an Institutional Pharmacy is a Residential Pharmacy.

(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 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90; Renumbered from 855-041-0105 by BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5015
Registration

All residential drug outlets shall register annually with the Board of Pharmacy. Residential drug outlets which also provide outpatient pharmacy services shall also register as retail drug outlets.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1980, f. & ef. 4-3-80; Renumbered from 855-041-0115 by BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

Technician Checking Validation Program (TCVP)

The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician performing as a technician checker.

855-041-5100
Definitions

(1) “Error” in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.

(2) “Error” in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.

(3) “Line Item” is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).

(4) “Technician Checker” is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician’s work.

(5) “Technician Checking Validation Program (TCVP)” is a program that uses a technician checker to check functions completed by another technician.

(6) “Unit Dose” is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged,

oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5120
Hospital and Pharmacist in Charge Requirements

(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:
(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.

(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;

(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and

(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.

(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:

(a) Copies of written training material that will be used to train technicians as technician checkers;

(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;

(c) Copies of the policy and procedures for the proposed TCVP; and

(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.

(e) Other items as requested by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5130
Technician Eligibility and Training

(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:

(a) A minimum of one year of drug distribution experience;

(b) Didactic lecture or equivalent training with a self-learning packet;

(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and

(d) Initial Validation Process as described in OAR 855-041-5140(1).

(2) The practical training sessions must include:

(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;

(b) The trainee performing the initial check with a pharmacist verifying all doses;

(c) The trainee completing the validation process with a pharmacist verifying all doses;

(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.

(e) The pharmacist must document and notify a technician checker of any errors found during training.

(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5140
Initial Validation Process and Quality Assurance Process

(1) Initial Validation Process: The initial process to validate a trainee's ability to accurately check another technician's work must include:

(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:

(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.

(b) The quality checks must occur on random and unannounced dates and times.

(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.

(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.

(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.

(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.

(5) A description of the quality assurance process must be included in the hospital's and the pharmacy's quality assurance program and error reporting system.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5150
Checking Procedure

(1) A technician checker must use the following procedure when checking another technician's work:

(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.

(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.

(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker

(d) If a technician checker is not available, then all doses must be checked by a pharmacist.

(2) This checking process continues until all doses have been checked and determined to be correct.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5160
Eligible Specialized Functions

(1) The following specialized functions are eligible for participation in the TCVP:

(a) Cart fill;

(b) ADC batch replacement; and

(c) Non-Emergent kits and trays.

(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5170
Records

(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

(a) Technician checker training documents;

(b) List of high risk medications;

(c) Documentation of any errors, irregularities and results of each initial validation check.

(d) Documentation of quality assurance and forms used to evaluate the technician checker including:

(A) Total number of doses or line item checks;

(B) Description of errors;

(C) Total number of errors; and

(D) Percent error rate.

(e) Documentation of the initial validation check.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

Hospitals with Pharmacies

855-041-6050
Definitions

(1) In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(a) “Automated Distribution Cabinet” (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;

(b) “Drug” means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(c) “Central pharmacy” means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;

(d) “Chief Pharmacy Officer” (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(e) “Drug profile” means a complete and comprehensive summary of a patient’s current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;

(f) “Licensed Independent Practitioner” (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;

(g) “Out-patient” means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;

(h) “Remote storage area” means a patient care area which is part of the hospital that is under the supervision and control of the hospital’s central pharmacy but is not located in the same building as the central pharmacy;

(i) “Secondary drug storage area” means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;

(j) “Unit-dose” means a quantity of a drug designed to be administered to a patient, such as:

(A) An oral solid individually packaged or re-packaged;

(B) An oral liquid drawn up in a labeled oral syringe;

(C) An injectable product; or

(D) A pre-mixed IV product.

(2) Not withstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6100
Registration

(1) Each central pharmacy must be registered with the Board. In a hospital with multiple central pharmacies, each pharmacy location must be registered with the Board.

(2) A secondary drug storage area within the hospital or in a structure physically attached to the hospital does not require a separate registration.

(3) A registered pharmacy in a hospital may use additional locations within the hospital, supervised by a pharmacist, without acquiring separate registrations for each additional location.

(4) A secondary drug storage area in a separate location must be registered as a drug room and must follow all rules that apply to secondary storage areas in the hospital.

(5) A residential healthcare facility that is licensed by DHS and that has a central pharmacy must register the pharmacy with the Board.
(6) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.305
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6150
General Pharmacy Requirements

(1) Each hospital pharmacy must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC).

(2) A hospital that has more than one pharmacy must designate an Oregon licensed pharmacist as CPO or an equivalent position who has responsibility for directing pharmacy services in the hospital. The CPO may also be the PIC of one of the pharmacies.

(3) A hospital pharmacy may only be operated when under the direct supervision of an Oregon licensed pharmacist. The pharmacist shall be responsible for all areas of the hospital where drugs are stored, including remote storage areas

(4) The pharmacy must be operated at least part-time, five days a week.

(5) The hospital pharmacy must have adequate space so that drugs can be prepared in sanitary, well-lit, enclosed places. Space and equipment must be adequate for the pharmaceutical services provided including compounding, distributing, and storage of drugs and parenteral preparations.

(6) As a minimum, the pharmacy must have the following:

(a) Equipment listed in OAR 855-041-0040, except that a pharmacy that is only registered as an institutional drug outlet does not need to have an Official Poison and Exempt Narcotic Register;

(b) A drug formulary approved by the appropriate hospital committee;

(c) Pharmacy policy and procedures.

(7) All areas occupied by a hospital pharmacy must be secured to prevent access by unauthorized personnel.

(a) Whenever any area of a hospital pharmacy is not under direct supervision of a pharmacist, the area must be secured;

(b) The CPO shall designate in writing, by title and specific area, those persons who may have access to specific areas within the pharmacy;

(c) Unless otherwise permitted by these rules, a non-pharmacist may not have access to the pharmacy unless a pharmacist is on duty and present in the hospital.

(8) A residential healthcare facility that has a central pharmacy must comply with these rules.

(9) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is in writing. A waiver is not valid for more than five years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Drug Distribution and Control

855-041-6200
Chief Pharmacy Officer and Pharmacist in Charge

(1) The CPO must specify the respective responsibilities of the CPO and the PIC if separate individuals hold these positions.

(2) In addition to the duties listed in this rule, the PIC has the responsibilities listed in OAR 855-019-0300.

(3) The CPO must establish policies and procedures that include:

(a) Procedures for general distribution of drugs throughout the hospital;

(b) A procedure for review and revision of the policies and procedures not less than every three years;

(c) Procedures for the supervision of pharmacy services including storage, distribution, control and accountability for drugs including controlled drugs;

(d) Procedures to ensure that all areas of the hospital where drugs are stored are inspected not less than every two months to verify proper drug storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and the integrity of the emergency drug supplies;

(e) Policies and procedures that govern the preparation, verification and sterilization of parenteral drugs compounded within the hospital. Procedures must comply with OARs 855-045-0200 through 855-045-0270 and these rules;

(f) Procedures for administration of drugs, including self-administration;

(g) Procedures for labeling drugs;

(h) Policies and procedures that govern the filling and labeling of containers from which drugs are to be administered;

(i) Procedures for a Quality Assurance program to ensure that there is a planned, ongoing and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services, and for identifying and resolving problems. Such monitoring and evaluation must be

accomplished through ongoing collection of information and periodic assessment of the collected information;

(j) Emergency drug distribution;

(k) Procedures for procurement of all drugs subject to approval of the appropriate committee of the hospital;

(l) Procedures to ensure that discontinued, outdated, adulterated or misbranded drugs are returned to the pharmacy for proper disposition, or that the PIC makes proper disposition or disposal of such drugs at the storage site;

(m) A recall procedure that can be quickly activated to assure the CPO and pharmacy staff, and the medical staff that all drugs included in the recall have been returned to the pharmacy for proper disposition;

(n) Policies and procedures for the use of investigational drugs;

(o) Procedures to be followed in the absence of the pharmacist.
(4) The CPO must:

(a) Participate in the development and revisions of a hospital formulary;

(b) Maintain an emergency and disaster plan for pharmacy services, and participate in the facility's emergency and disaster plan;

(c) Ensure that records of all transactions of the hospital pharmacy that are required by state and federal laws and regulations are maintained, and maintain accurate control and accountability for all pharmaceutical materials;

(d) Participate in the hospital's Quality Assurance program related to drugs;
(e) Comply with all inspection and other requirements of the pharmacy in accordance with all applicable state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6220
Records

(1) Unless specified otherwise, all records and documentation required by these rules, OAR 855-041-6000 through 855-041-6999 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:

(a) Patient profiles and drug administration records;

(b) Reports of suspected adverse drug reactions;

(c) Inspections of drug storage areas;

(d) Annual controlled substance inventories;

(e) Controlled drug accountability reports;

(f) Collaborative Drug Therapy agreements;

(g) Current hospital drug formulary;

(h) Any other records and reports required by state and federal laws and regulations.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.508
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6240
Drug Administration

(1) In a hospital, a drug may only be administered upon an order initiated by:

(a) A member of the medical staff who has been granted clinical privileges;

(b) An authorized member of the house staff; or

(c) An authorized licensed practitioner.

(2) Each administration of a drug must be in accordance with policies and procedures approved by the appropriate committee of the hospital, must comply with all applicable laws, rules and regulations, and must follow usual and customary standards of good medical practice.

(3) Self-administration. A patient may only be permitted to self-administer a drug when specifically authorized by the treating or ordering practitioner, and when the patient has been educated and trained in the proper self-administration of the drug.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6250
Patient's Own Drugs and Other Drugs from Outside Sources

When a patient or a patient's agent brings a drug into the hospital, the drug may only be administered to the patient if:

(1) The practitioner or pharmacist has identified it and it is in a pharmacy labeled container; and

(2) Any administration is pursuant to a practitioner's order; or

(3) In the pharmacist's professional judgment, withholding the drug would be detrimental to the patient's health. In such a case, the pharmacist may authorize administration of the drug pursuant to a practitioner's order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6260
Investigational Drugs

(1) All in-patient investigational drugs must be stored in the pharmacy and may only be distributed from the pharmacy when properly labeled.

(2) Information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs must be available in the pharmacy.

(3) Investigational drugs may only be ordered by a designated physician-investigator or their authorized clinician, subject to the prior approval of the appropriate hospital committee.

(4) Each order must include the appropriate protocol number.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6270
Labeling

(1) Each pharmacy record keeping system must identify and document the pharmacist who verifies the drug.

(2) Each pre-packed drug, including a unit-dosed drug, prepared by the pharmacy and intended for use within the facility shall be in an appropriate container with a label that contains:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is to be sent with the patient upon discharge must be labeled in accordance with ORS 689.505(5) and other rules in this Division. Drug counseling information must be provided to the patient or patient's agent.

(5) A label for an outpatient prescription must comply with ORS 689.505(5) and other rules in this Division.

(6) New bar coding or electronic label: When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(7) Whenever a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that contains

(a) The name, quantity and concentration of the drug added and the primary solution;

(b) The date and time of addition;

(c) The expiration date;

(d) The scheduled time for administration;

(e) The infusion rate, when applicable;

(f) The name or initials of person performing admixture;

(g) The identification of the pharmacy where the admixture was performed; and

(h) The name or initials of the verifying pharmacist.

(8) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.505
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Absence of a Pharmacist

855-041-6300
Untitled

The CPO must make appropriate arrangements for provision of drugs to the medical staff and other authorized personnel by use of a night cabinet or by access to the pharmacy, or both, for situations when hospital pharmacy services are not available.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.605
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6305
Night Cabinet

(1) If a night cabinet is used, the following procedures must be followed:

(a) The cabinet or other enclosure located outside the pharmacy must be secure from unauthorized access;

(b) Only one authorized registered nurse on a shift may have access to the night cabinet and may remove drugs. Such nurse must be designated in writing by the appropriate committee of the hospital and prior to being given access to the night cabinet, must receive appropriate training in the proper procedures for access, removal of drugs, and recordkeeping;

(c) The PIC or designee must give this training, and must require, at a minimum, the following procedures:

(A) A drug may only be removed from the night cabinet on a practitioner's written order or a verbal order that has been reduced to writing;

(B) A copy of the practitioner's order must be left in the night cabinet for the pharmacist to verify for accuracy. Both the nurse supervisor and the verifying pharmacist must initial the order.

(2) In conjunction with the appropriate hospital committee, the CPO must develop an inventory of those drugs to be included in each cabinet and establish procedures to ensure that:

(a) Drugs are available and labeled as required by these rules;

(b) Only prepackaged drugs are placed in the cabinet;

(c) Quantities do not exceed those reasonable for immediate therapeutic requirements;

(d) Whenever a cabinet has been accessed, a written record is kept of the drug order and certification of the drug use;

(e) Controlled substances are kept securely and are accounted for using a reconciled perpetual inventory;

(f) An audit of controlled substances in the cabinet is conducted at least once per month. If a tamper-evident seal system is not used, a quality assurance program must be in place to identify any diversion.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.605
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6310
After Hours Access to Pharmacy

When a drug required to treat the immediate needs of a patient is not available from floor-stock or a night cabinet, it may be obtained from the pharmacy in accordance with the following procedures:

(1) Only one registered nurse supervisor on a shift may have access to the pharmacy and may remove drugs. The nurse supervisor must be designated in writing by the appropriate hospital committee and prior to being permitted to obtain access to the pharmacy, must receive appropriate training in the proper procedures for access, removal of drugs, and recordkeeping;

(2) The PIC or designee must give such education and training, and must require, at a minimum, the following procedures:

(a) A drug may only be removed from the pharmacy on a practitioner's order that has been posted to the patient’s medical record;

(b) A copy of the practitioner's order must be left either with the container from which the drug was removed or with an identical unit-dose, and must be placed conspicuously for a pharmacist to verify for accuracy;

(c) A record of each drug removed from the pharmacy by the nurse supervisor must include:

(A) Name and hospital location of the patient;

(B) Name and strength of drug distributed;

(C) Units used;

(D) Date and time of distribution;

(E) Initials of the nurse supervisor distributing the drug;

(F) Date and initials of the pharmacist who confirmed the accuracy of the transaction.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.605
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6400
Emergency Dispensing by a Nurse

A hospital may provide for the emergency dispensing of a drug to an outpatient who is under the care of a practitioner who is a member of the hospital medical staff, when there is a legitimate medical need as described in hospital policies and procedures.

(1) A designated registered nurse may dispense a drug to an outpatient subject to the following:

(a) There is a prescription from a practitioner authorized to prescribe the drug or a verbal order that the nurse has reduced to writing. A practitioner who issues a verbal order or prescription must send a written prescription to the hospital pharmacy within seven days;

(b) The drug is in a manufacturer's bulk unit-of-use, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with;

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the name of the manufacturer or distributor;
(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug;

(E) Name, address and phone number of the hospital pharmacy.

(c) The following information must be added to the drug container by the nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number;

(E) Name of prescribing practitioner;

(F) Initials of the dispensing nurse or practitioner.

(d) The patient must be given instructions on the use and precautions for taking the drug;

(e) A prescription must be completed by the practitioner or nurse. This prescription must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Name and strength of drug distributed;

(D) Units issued;

(E) Name of practitioner and initials of dispensing nurse;

(F) Instructions given to the patient.

(f) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient.

(2) The patient may not be given more than an emergency supply, as that is defined in the hospital policy and procedures.

(3) The pharmacist must verify, document and date the original prescription.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.505
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6410
Emergency Department Distribution

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:
(a) The prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient’s choice.

(b) During consultation with the patient or the patient’s caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient’s choice.

(c) The patient must be given instructions on the use and precautions for taking the drug;

Labeling

(d) The drug is in a manufacturer’s unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

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

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug; and

(E) Name, address and phone number of the hospital pharmacy.

(e) The following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number as determined by policy and procedure;

(E) Name of prescribing practitioner; and

(F) Initials of the dispensing nurse or practitioner.

Distribution Record

(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Drug name and strength distributed;

(D) Units issued;

(E) Name of practitioner;

(F) Initials of the dispensing nurse or practitioner; and

(G) Instructions given to the patient as labeled.

(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;
(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist shall review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and

(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the Board.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each prepak that may be distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount dispensed may not exceed a 48 hour supply except for:
(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;

(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;

Automated Dispensing Machine

(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.

(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;

(7) When the patient or patient's representative receives the prescription from an ADM;

(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and

(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the

drugs to be dispensed using a password protected or biometric security system; and

(c) The patient or patient's representative will obtain the drug using a specific patient access code.

(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.

(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.

(10) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing and will be time limited.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.505
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10; BP 8-2012, f. & cert. ef. 12-21-12

In-Patient Drug Distribution

855-041-6420
Emergency Kit and Code Cart

An emergency kit consists of those drugs which may be required to meet the immediate therapeutic needs of in-patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

(1) An emergency kit may be placed in a code cart or as a stand-alone emergency kit.

(2) A pharmacist must verify and document the contents of each emergency kit.

(3) The CPO in cooperation with the appropriate hospital committee shall determine the list and quantity of drugs to be included in an emergency kit. The CPO must ensure that this list is reviewed annually.

(4) An emergency drug kit must use a tamper-evident system and be stored to prevent unauthorized access.

(5) All drugs in emergency kits and code carts must be labeled in accordance with OAR 855-041-6270.

(6) An emergency kit or code cart must be labeled to indicate that it is a drug supply for emergency use. A label must also contain the name, strength, quantity of all drugs in the kit or code cart and the expiration date of the kit. The label shall be affixed to or be available on the exterior of the code cart.
(7) The expiration date of an emergency kit or code cart must be the same as the earliest expiration date of any drug in the kit or cart. Prior to the expiration date, the pharmacist must replace expired drugs.

(8) Only an authorized person may remove a drug from an emergency kit or code cart. Any removal must be pursuant to a valid order or approved protocol.

(9) The pharmacy must be notified when an emergency kit or code cart has been opened or has expired and the pharmacist must restock or replace the emergency kit within a reasonable time.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6500
Practitioner's Drug Order

(1) An order for a drug for an in-patient must be transmitted to the pharmacy using a system that produces a direct or an electronic copy.
(2) A pharmacist must review the drug order before the initial dose is dispensed, and must document the review and DUR except:

(a) When a drug is dispensed under OAR 855-041-6310;

(b) In an emergency;

(c) When pharmacy services are not available; or

(d) When a LIP is present.

(3) An order for a drug must contain:

(a) The patient's name and location;

(b) The drug name and strength;
(c) Route of administration;

(d) Directions for use;

(e) The date and time; and

(f) The practitioner's written or electronic signature, or the signature of the practitioner's agent.

(4) The hospital must follow the following procedures for verbal drug orders:

(a) A verbal drug order should be used infrequently;

(b) A verbal drug order of an authorized individual may be accepted and transcribed only by a qualified person who has been identified by title or category in the hospital policies and procedures;

(c) A verbal order must be reduced to writing and read back to the prescribing practitioner to verify accuracy;

(d) A verbal order must be signed or initialed by the prescribing practitioner as soon as possible.

(5) A drug administered to a patient must be ordered by an authorized prescribing practitioner or otherwise allowed by these rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6510
In-patient Drug Profile

(1) Each pharmacist must ensure that a drug order for a patient requiring continuous drug therapy is entered into the patient's drug profile. The profile must contain:

(a) The patient's name, location and important clinical data such as age, height, weight, sex, chronic disease states, problem list and allergies;

(b) The drug name, strength, dosage form, route of administration and directions for administration;

(c) The drug therapy start and end date as applicable;

(d) The name or ID of the pharmacist responsible for entry or verification of the drug order.

(2) Prior to the drug being released for access by the nurse, a pharmacist must enter the drug order into a drug profile and perform a DUR except when:

(a) The drug is being dispensed from an after-hours cabinet in the absence of a pharmacist;
(b) The drug is from an emergency drug kit; or

(c) A system override is being used by a LIP or nurse to treat the emergency needs of a patient. Subject to a prescriber's order, a sufficient quantity to meet the emergency needs of the patient may be used until a pharmacist is available to review and confirm the drug order.

(3) The pharmacist must continue to monitor the appropriateness of the patient's drug utilization throughout the patient's stay in the hospital.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6520
Cart-Fill

(1) A unit-dose cart-fill system is a pharmacy controlled unit-of-use drug distribution system.

(a) A unit-dose cart-fill system must provide for separation of drugs by patient name and location, and must be designed to record in an individual patient's record:

(A) The drug, dose strength, and dosing regimen of those drugs dispensed by the pharmacy;

(B) The number of doses dispensed;

(C) The date of the original order, and the date the order is discontinued.

(b) The system must:

(A) Provide a means for the pharmacist to verify the prescriber's original order;

(B) Provide a means for the pharmacist to verify the accuracy of the selected drug before the dose is delivered for administration to the patient; and

(C) Provide a mechanism to identify controlled substances.

(c) The pharmacist must verify the prescriber's original order and the accuracy of the selected drug.

(2) Controlled substances may be included in the unit-dose system if the system complies with all applicable state and federal laws and regulations.

(3) Each drug must be in unit-dose packaging when dispensed except when this is impracticable.

(4) A drug not dispensed in unit-dose packaging must be labeled in accordance with other rules in this Division.

(5) A drug in a single container multiple-dose package such as an inhaler or a topical drug must be labeled with the patient's name and location within the facility.

(6) A pharmacy technician, certified pharmacy technician, intern or pharmacist may fill daily unit-dose drug supplies for a hospital in-patient or a nursing home patient.

(7) The pharmacist must verify the accuracy of a unit-dose package before the dose is delivered for administration to the patient.

(8) Each drug must be stored in a locked area or locked cart.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6530
Robotic Distribution Systems

(1) A robotic drug distribution system used in a central pharmacy must be in a secure area under the control of the PIC and must be connected with the system that contains the patient's drug profile.

(2) The pharmacy must maintain the following documentation for each system:

(a) Details of the equipment including manufacturer's name, model and serial number;

(b) A description of how the system is used;

(c) Policies and procedures that include:

(A) Quality assurance performed at least quarterly including a requirement that a pharmacist visually verifies the accuracy of the electronic or bar code labeling using an audit procedure that includes random sampling;

(B) Procedures for training personnel in safe system operation, security, accuracy, patient confidentiality, access and downtime procedures.

(3) All distribution records must be recorded electronically and retained for 3 years or as approved by the Board. Records must include:

(a) Identity of robotic drug distribution system accessed;

(b) Type of transaction;

(c) Date and time of transaction;

(d) Name, strength, dosage form, and quantity of the drug accessed;

(e) Identity of the patient for whom the drug was ordered;

(f) Any other information the PIC may deem necessary.

(4) Only a pharmacy technician, certified pharmacy technician, intern, pharmacist or a person designated by the PIC may have access to the system.

(5) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may stock drugs in the system.

(6) All drugs in the system must be packaged and labeled in accordance with state and federal laws and regulations.

(7) Controlled Substances:

(a) Controlled substances must be handled in accordance with all applicable state and federal laws and regulations;

(b) Schedule III, IV and V drugs may be stocked in a robotic drug distribution system provided there is adequate security to limit access to those personnel designated by the PIC;

(c) Schedule II drugs may not be stocked in any robotic drug distribution system.

(8) Drugs prepared by a robotic system must be packaged and separated by patient or as approved by hospital protocol, prior to distribution for administration.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.508
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6540
Automated Distribution Cabinets

(1) Each ADC must be under the control of the pharmacy. The PIC must establish policies and procedures to meet the requirements of all applicable state and federal laws and regulations.

(2) Policies and procedures addressing the operation of the ADC must be maintained in the pharmacy. They must include:

(a) Training of personnel granted access to the ADC;

(b) System operation, safety, security, access, accuracy and patient confidentiality;

(c) Cabinet replenishment procedures;

(d) Downtime procedures;

(e) A procedure for securing and accounting for any wasted, discarded or unused drug in accordance with existing state and federal laws and regulations.

(3) All events involving the contents of the ADC must be recorded and must include:

(a) Identity of ADC accessed;

(b) Identification of the individual accessing the ADC;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form and quantity of the drug accessed;

(f) Name of the patient or patient identifier for whom the drug was ordered;

(g) Such additional information as the PIC may deem necessary.

(4) Only a pharmacist, pharmacy technician, certified pharmacy technician, intern or other person designated by the PIC may have access to the ADC.

(5) Stocking drugs in an ADC:

(a) Only a pharmacy technician, certified pharmacy technician, intern, pharmacist or other licensed healthcare personnel designated by the PIC may stock drugs in the ADC;

(b) A pharmacist must visually or electronically verify the name, strength and accuracy of the drug to be released from the central pharmacy for restocking;

(c) When a barcode or other electronic system is used to confirm the accuracy of the replenishment of the stock in an ADC, the system must receive an initial quality assurance validation;

(d) When all drug doses for an individual storage unit or bin have been packaged in one container, a single barcode verification may be used;
(e) The PIC must monitor the accuracy of the replenishment of drugs with a quality assurance process that includes:

(A) Reconciling the ADC fill list with established unit specific drugs using the drug profile, ADC discrepancy and inventory reports; and

(B) Monitoring the accuracy of the restocking and withdrawal procedures used by all hospital staff approved for drug administration.

(f) The PIC may permit medical supplies and devices to be included in the ADC.

(6) All drugs stored in the ADC must be packaged and labeled in accordance with state and federal laws and regulations.

(7) A drug that has been removed from the ADC for any purpose may not be returned to the system unless:

(a) A pharmacist has examined the drug, the packaging, and the labeling and determined that reuse of the drug is appropriate; or

(b) It is a drug, such as a multi-dose vial, which has been exempted by the appropriate hospital committee.

(8) At the time of loading, unloading, inventorying, removing or accessing any controlled substance from the ADC, a blind count or confirmation of the correct count must be conducted. Any discrepancy must be reported immediately to the PIC or pharmacist on duty who is responsible for reconciliation of the unresolved discrepancy or proper reporting of the loss.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6550
Secondary and Remote Storage

(1) All drugs must be stored in designated areas to ensure proper sanitation, temperature, light, ventilation, moisture control, and security.

(2) Drugs may only be stored in nursing units when space is available for the storage, security, and preparation of drug doses. Such space must include:

(a) A locked drug cabinet or room that is equipped so that each patient’s drugs are separated physically or electronically. Drugs may be stored in secured individual patient storage areas or individually labeled for each patient;

(b) A container or compartment that is permanently attached to a storage cart or the drug room in which controlled substances can be secured;

(c) Alcohol and other flammables must be stored in areas that meet local building code requirements for the storage of volatiles, and such other laws and regulations that apply.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Floor-stock and Non–emergency Trays and Kits

855-041-6560
Floor-Stock

(1) A minimal quantity of drugs may be stocked in patient care areas to meet the immediate therapeutic needs of a patient where delay would interrupt the continuity of, or compromise the care of the patient.

(2) A hospital pharmacy must not use a floor-stock drug distribution system as its primary system of drug distribution except in departments staffed with a LIP such as the Emergency Room, Operating Rooms and Radiology.

(3) The CPO, in consultation with nursing staff, must prepare a list of drugs by identity and quantity for each area where such supplies are stocked. This list must be kept in the pharmacy.

(4) Floor-stock drug supplies must be stored in a secure area only accessible to pharmacy-authorized personnel.
(5) All drugs in floor-stock must be labeled in accordance with other rules in this Division.

(6) Drugs may only be removed from floor-stock by personnel authorized by the appropriate hospital committee. A drug may only be removed pursuant to a valid prescriber's order. Removal from stock must be recorded in accordance with policy and in the patient's medical record.

(7) The CPO may permit medical supplies and devices to be included in the floor-stock.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6570
Trays and Kits

(1) All drug trays and kits must be prepared by the pharmacy prior to release from the central pharmacy except that trays and kits may be prepared from floor-stock by an LIP who administers the drug or by authorized hospital staff in the case of emergency use if:

(a) The pharmacy and appropriate hospital departments jointly develop guidelines for the proper use, preparation, and security for the trays or kits; and

(b) The pharmacy has a quality assurance program for monitoring the proper use, preparation and security of the kits.

(2) A pharmacist must verify the accuracy and secure the contents of each tray or kit prepared in the pharmacy prior to release from the central pharmacy.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

Controlled Substances

855-041-6600
Controlled Drug Accountability
(1) The hospital must establish procedures and maintain records to account for all controlled substances and any other drugs designated by the appropriate hospital committee. Records must include:
(a) Name of drug;

(b) Dose ordered, dose dispensed, and dose administered;

(c) Identity of patient;

(d) Date and time of administration;

(e) Person administering the drug;

(f) Verification and documentation of any wasted drug including partial doses.

(2) The pharmacy must provide separately locked, securely affixed compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single-unit packaged drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(3) The pharmacy must obtain a delivery receipt for all controlled drugs supplied as floor-stock. This record must include the date, drug name and strength, quantity, hospital unit receiving drug and the signatures of the distributing pharmacist and the receiving nurse.

(4) A record must be kept of each administration of a controlled drug from floor-stock. The record must be returned to the pharmacy monthly and the PIC or designee must:

(a) Match returned records with delivery receipts to verify that all records are returned;

(b) Periodically audit administration records for completeness;
(c) Reconcile administration records with inventory and verify that sums carried from one record to the next are correctly recorded;

(d) Periodically verify that doses documented on administration records are reflected in the medical record; and

(e) Initial the returned record and file by date of issue.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165 & 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6610
Schedule II Drugs

(1) In addition to the requirements above, Schedule II record keeping must include:

(a) A perpetual inventory system for all Schedule II drugs received, stored and distributed by the pharmacy. The perpetual inventory must be reconciled with an actual inventory at least monthly and the results and any discrepancies must be noted;

(b) Schedule II drugs stored as floor-stock in patient-care areas must be controlled with a perpetual inventory system that includes an actual inventory count and reconciliation when the department or nursing unit is open. The CPO must develop policies and procedure to ensure a regular audit of the inventory;

(c) Quality assurance procedures for the random sample of perpetual inventory sheets including sign-out sheets or other dose-by-dose documentation, must be performed at least quarterly and must be used to determine the accuracy and effectiveness of Schedule II floor-stock drug control;
(d) All Schedule II drugs stored in the pharmacy must be kept in a locked area or secured storage system that tracks the identity of each person making entry into and out of the system whenever a pharmacist is not physically present in the department.

(2) Policies and Procedures must specify the conditions under which Schedule II controlled substances can be transferred into or removed from an ADC.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165 & 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6620
Electronic Safe Systems

(1) The pharmacy must maintain policies and procedures that address the operation of any electronic safe system. These policies must include:

(a) Training of personnel granted access to the electronic safe system;
(b) System operation, safety, security, access, accuracy and patient confidentiality;

(c) Downtime procedures.

(2) All events involving the contents of the electronic safe system must be recorded electronically. Such records must include:

(a) Identity of electronic safe system accessed;

(b) Identification of the individual accessing the electronic safe system;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form, and quantity of the drug accessed;

(f) Name of the patient for whom the drug was ordered when applicable;

(g) Any additional information that the CPO requires.

(3) Only a pharmacist, pharmacy technician, certified pharmacy technician or intern may have access to the electronic safe system.

(4) Only a pharmacist, pharmacy technician, certified pharmacy technician or intern may stock drugs in the electronic safe system.

(5) All activities involving the electronic safe system must comply with all applicable state and federal laws and regulations.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.165 & 689.155
Hist.: BP 3-2010, f. 4-29-10, cert. ef. 4-30-10

855-041-6800
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 855-041-6420;

(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 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 689.205
Stats. Implemented: ORS 689.205
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; Renumbered from 855-041-0135, BP 7-2012, f. & cert. ef. 12-17-12

855-041-6840
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; Renumbered from 855-041-0140, BP 7-2012, f. & cert. ef. 12-17-12

Pharmacists Serving Long Term Care Facilities and Community Based Care Facilities

855-041-7050
Definitions

As used in OAR 855-041- 7000 through 855-041- 7080:

(1)(a) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(b) For the purposes of Schedule II prescriptions in 21 CFR 1306.11-1306.13, the DEA definition of "long term care facility" as defined in 21 CFR 1300.01(25) includes "community based care facilities."

(2) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.

(3) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:

(a) Develop and maintain policies and procedures for pharmaceutical services;

(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:

(A) Receipt and interpretation of physician's orders;

(B) Ordering and receiving of medications;

(C) Handling of emergency drugs and supplies;

(D) Labeling of all drugs;

(E) Selection of drug delivery systems;

(F) Development of systems to provide timely delivery of drugs and supplies;

(G) Monitoring of drug storage conditions and expiration dates;

(H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;

(I) Establishing and monitoring of appropriate record keeping;

(J) Accountability of controlled substances;

(K) Return, release, and/or destruction of discontinued or outdated drugs; and

(L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.

(c) Provide training and in-service education to facility staff;
(d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:

(A) Over-utilization or underutilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug, drug dosage or duration of drug treatment;

(F) Drug-allergy interaction;

(G) Clinical abuse/misuse;

(H) Untreated indication;

(I) Monitoring and assessing of drug therapy outcomes;

(e) Communicate effectively with residents' physicians and facility staff; and

(f) Participate in resident care planning.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.0305
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 8-1990, f. & cert. ef. 12-5-90; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-041-0145, BP 7-2012, f. & cert. ef. 12-17-12

855-041-7060
Drug Distribution and Control

(1) Pharmacies or pharmacists that supply emergency drug kits to and/or accept returned medications from long term care facilities or community based care facilities must:

(a) Assist in the establishment and supervision of:

(A) The policies and procedures for the safe storage, distribution, administration, and disposition of drugs;

(B) The maintenance of controlled drug accountability records; and

(C) The policies and procedures for professional advice/medication counseling of patients and/or their care givers.

(b) Have some pharmacists visit and provide consultant services on a regular basis; and

(c) Supervise the implementation of the policies and procedures involving the security, storage, stocking, labeling, and notification of use of emergency drugs kits and supplemental drug supplies.

(2) Arrangements can be made in advance by a provider pharmacy with a long term care facility or a community based care facility to:

(a) Provide emergency drug kits to those facilities permitted by their license to have them; and

(b) Allow only a designated licensed nurse present in the facility access to the emergency drug kit or the on-site pharmacy pursuant to OAR 855-041-6310.

(3) An emergency drug kit consists of those drugs that may be required and are authorized by a practitioner to meet the immediate therapeutic needs of patients, when medication is not readily available directly from a pharmacy.

(4) The emergency drug kit inventory is the property of the provider pharmacy, and the provider pharmacy consultant is responsible for developing the policy and procedures for storing and stocking the emergency drug kit.

(5) Medication(s) can only be removed from the emergency drug kit or the on-site pharmacy by a designated licensed nurse pursuant to a practitioner's order.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: 1PB 2-1980, f. & ef. 4-3-80; 1PB 1-1981(Temp), f. & ef. 4-1-81; 1PB 2-1981, f. & ef. 8-20-81; PB 1-1990, f. & cert. ef. 1-23-90; PB 8-1990, f. & cert. ef. 12-5-90; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-041-0160, BP 7-2012, f. & cert. ef. 12-17-12

855-041-7070
Labeling and Distribution

(1) Except as provided in subsection (2) of this section, all drugs dispensed for individual patients must be labeled as required by OAR 855-041- 1120, or administered by health care professionals from a unit dose system as defined in OAR 855-041- 6050(j).

(2) Pharmacies that provide long term care facilities or community based care facilities with pharmaceuticals can supply, on the order of a practitioner, and consistent with the policy and procedures of the pharmacy or pharmacist providing consultant services:

(a) Injectables for immunization and screening;

(b) Irrigation solutions; and

(c) Bulk manufacturer's container(s) of topical scabicides and pediculicides.

(3) Institutional pharmacies that dispense medications to patients in long term care facilities and community based care facilities must maintain for three years the records required by OAR 855-041-1120, and comply with the patient counseling requirements of OAR 855-19-0230.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-041-0162, BP 7-2012, f. & cert. ef. 12-17-12

855-041-7080
Pharmaceutical Care in Community Based Care Facilities

When a pharmacist provides pharmaceutical care to patients in a Community Based Care facility under an arrangement with the facility, the pharmacist may provide the following services:

(1) Assist facilities in establishing the appropriate policies and procedures for distribution, storage, documentation and disposal of drugs;

(2) Assist facilities in establishing and maintaining proper record keeping related to medication administration;

(3) Visit the facility on a regularly scheduled basis;

(4) Supervise the distribution and storage of drugs;

(5) Assist in providing appropriate training, in-service education, and clinical support to facility staff; and

(6) Communicate with physicians and other practitioners as needed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-041-0164, BP 7-2012, f. & cert. ef. 12-17-12

Home Health Care Agencies

855-041-8050
Emergency Drug Supply in Home Health Care Agencies

Pharmacists serving home health care agencies may provide for an emergency supply of drugs to be made available to registered nurses to treat immediate therapeutic needs of their patients or clients during such time as the pharmacy services are not available. Arrangements shall be made in advance by the provider pharmacist for provision of the emergency drug supply:

(1) Emergency drugs defined. Emergency drugs are those non-controlled substances which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in a timely manner;

(2) Portable Container. Subject to all provisions of this section, a licensed pharmacy may furnish to a home health agency licensed by the State an emergency drug supply in a portable container for emergency in home treatment or adjustment of drug therapy by the home health agency nurse;

(3) Drugs included. The pharmacist(s) and the practitioner(s) who represent the agency shall jointly determine and review annually a list of items and quantities to be included in the emergency supply. Drugs shall only be available therein, in amounts sufficient for immediate therapeutic requirements. The selected list shall include only drugs to treat the following specific conditions:

(a) Allergic reactions;

(b) Diabetic emergencies;

(c) Severe nausea and vomiting;

(d) Pulmonary congestion or congestive heart failure;

(e) Local or topical anesthetics for catheter and needle placement;

(f) Hydration due to hypovolemia or shock;
(g) Routine catheter maintenance; and

(h) Narcotic analgesic overdose.

(4) Security. The emergency drug supply shall be stored in a manner to prevent loss of drugs, and available only to authorized licensed personnel. It may be kept in a room adjacent to the locked pharmacy, or in a secure area in the Home Health/Home I.V. nursing office;

(5) Storage. The emergency drug supply shall be stored in areas suitable to prevent unauthorized access and to insure a proper environment for preservation of the drugs as required in official compendia;

(6) Labeling-Exterior. The exterior of the emergency drug supply shall be labeled to clearly indicate it as an emergency supply. Labeling shall also include the expiration date of the drug supply. A complete listing of the contents of the supply shall be readily available;

(7) Labeling-Interior. All drugs contained in the emergency medication supply shall in the manufacturer's container or be labeled in accordance with OAR 855-041-1135;

(8) Drugs added to parenteral solutions. Whenever any drug is added to a parenteral solution, whether within or outside the direct personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of person so adding. This excludes any single dose medication prepared and totally administered immediately;

(9) Removal of drugs. Emergency drugs shall be removed for administration only by authorized licensed personnel pursuant to a prescriber's order. A copy of this order shall be forwarded to the provider pharmacist within 72 hours to be reviewed and filed in the pharmacy. Verification of this review shall be a hand written initial of the reviewing pharmacist on that copy of the order;

(10) Expiration Date. The expiration date of the emergency drug supply shall indicate the month and year, and shall be the earliest expiration date of any drug in the supply. The provider pharmacist shall examine the supply and replace drugs prior to their expiration.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.225
Hist. PB 1-1996, f. & cert. ef. 4-5-96; Renumbered from 855-041-0183; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-041-0165, BP 7-2012, f. & cert. ef. 12-17-12

BOARD OF PHARMACY

DIVISION 42
NUCLEAR PHARMACIES AND PHARMACISTS

855-042-0005
Purpose and Scope

(1) Any person who provides radiopharmaceutical services shall be a nuclear pharmacist or working under the supervision of a nuclear pharmacist and shall act in accordance with the State Board of Pharmacy and State Radiation Control Agency rules.

(2) These rules shall not apply to anyone who is an "authorized practitioner" as that term is defined in these rules.

(3) The requirements imposed by these nuclear pharmacy rules shall apply in addition to, and not in place of, any other requirements contained in rules of the State Board of Pharmacy, the State Radiation Control Agency, or any other state or federal agency.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

855-042-0010
Definitions

(1) A "Nuclear Pharmacy" is a pharmacy providing radiopharmaceutical services.

(2) "Nuclear Pharmacist" means a licensed pharmacist who has met the requirements of these rules regarding training, education, and experience, and has received a letter of notification from the board indicating the board recognizes the pharmacist, based on evidence submitted, as qualified to provide radiopharmaceutical services.

(3) "Radiopharmaceutical Services" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery or radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A "Radiopharmaceutical" is any substance defined as a drug in Section 201(g)(1) of the federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(6) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.
(7) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) "Authorized Practitioner" means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

855-042-0015
Nuclear Pharmacies

(1) Every nuclear pharmacy shall have a nuclear pharmacist designated on the nuclear pharmacy registration as the pharmacist-in-charge who shall be responsible for the nuclear pharmacy's compliance with laws and rules, both state and federal, pertaining to the practice of nuclear pharmacy. All personnel performing tasks in the preparation and distribution of 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 nonradio-pharmaceuticals and shall be secured from access by unauthorized personnel. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency before approval of the registration.

(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with accepted professional standards of radiopharmaceutical quality assurance.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable rules of the state Board of Pharmacy, the State Radiation Control Agency and other state and federal agencies.

(5) For nuclear pharmacies handling radiopharmaceuticals exclusively, the State Board of Pharmacy may waive regulations pertaining to the pharmacy registration for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(6) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(7) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(8) Prescriptions or medication orders for radiopharmaceuticals shall include:

(a) The name of the practitioner and/or institution;

(b) The name of the radiopharmaceutical;

(c) The amount of radioactivity to be contained in millicuries, microcuries, or the SI equivalent at calibration;

(d) The date and time of calibration, and volume.

(9) In addition to any labeling requirements of the state Board of Pharmacy for nonradiopharmaceuticals, the outer container of any radiopharmaceutical to be dispensed shall also be labeled with:

(a) The prescription number and the patient's name (of the words **"Physician Use Only"** in the absence of the name of the patient);

(b) The standard radiation symbol;

(c) The words **"Caution -- Radioactive Material"**;

(d) The name of the radiopharmaceutical;

(e) The lot number;

(f) The amount of radioactive material contained in millicuries, microcuries, or their SI equivalent;

(g) If a liquid, the volume in milliliters;

(h) The requested calibration date and time; and

(i) Expiration date and/or time, if applicable;

(j) Specific concentration of radioactivity;

(k) The name and address of the practitioner and/or institution that ordered the radiopharmaceuticals.

(10) The immediate inner container of a radiopharmaceutical shall be labeled with:

(a) Standard radiation symbol;

(b) The words **"Caution -- Radioactive Material"**; and

(c) The name and prescription number of the radiopharmaceutical;

(d) The prescription number;

(e) The name of the nuclear pharmacy;

(f) The date; and

(g) The amount of radioactive material in millicuries, microcuries, or their SI equivalent.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA (New Drug Application) approved radiopharmaceuticals to authorized persons if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and rules of the State Board of Pharmacy and State Radiation Control Agency.

(14) The nuclear pharmacy shall maintain a reference library commensurate with the level of radiopharmaceutical service to be provided and shall include, in addition to the requirements listed in OAR 855-041-0040;

(a) Oregon radiation control regulations;

(b) **CFR Title 10, Parts 0-199**, with current amendments; and

(c) **CFR Title 49, Parts 106-199**, with current amendments.

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87; PB 1-1994, f. & cert. ef. 2-2-94

855-042-0025
Minimum Equipment Requirements

(1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the State Board of Pharmacy and Radiation Control Agency before approval of the license.

(2) The State Board of Pharmacy may, for good cause shown, waive rules pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: PB 7-1987, f. & ef. 7-8-87

BOARD OF PHARMACY

DIVISION 43
PRACTITIONER DISPENSING

855-043-0002
Definitions

In this division of rules:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient at the direction of the practitioner.

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

(3) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the Board or by the Department of Human Services (DHS).

(4) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or DHS.

(5) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: PB 2-1992, f. & cert. ef. 3-26-92; PB 4-1992, f. & cert. ef. 8-25-92; Renumbered from 855-043-0120 by BP 1-2010, f. & cert. ef. 2-8-10; BP 3-2012, f. & cert. ef. 6-19-12

855-043-0003
Expedited Partner Therapy

(1) Expedited Partner Therapy (EPT) means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) An EPT prescription may only be dispensed for a drug and a disease that has been determined by DHS to be appropriately addressed by EPT.

Stat. Auth.: ORS 689.205
Stats. Implemented: 2009 OL Ch 522
Hist.: BP 1-2010, f. & cert. ef. 2-8-10

855-043-0005
Practitioner Labeling

All drugs dispensed by a practitioner must be labeled with the following information:

(1) Name, address and telephone number of the practitioner;

(2) Date;

(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;

(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;

(5) Direction for use;

(6) Required precautionary information regarding controlled substances;

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

(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drugs dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.

(9) Not withstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, ORS 689.505 & 2009 OL Ch 522
Hist.: PB 4-1992, f. & cert. ef. 8-25-92; Renumbered from 855-043-0001 by BP 1-2010, f. & cert. ef. 2-8-10

Nurse Practitioner Dispensing

855-043-0210
Purpose and Scope

The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:

(1) Documented review of content regarding safe dispensing listed below:

(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";

(b) The Drug Enforcement Administration Pharmacist's Manual (2004);

(c) OAR 851, division 56;

(d) ORS Chapter 689 and OAR chapter 855;

(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"

(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov. 2006); and

(g) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications

(2) Successful self examination as provided by the Board of Nursing on these materials.
[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 678.390 & 689.205
Stats. Implemented: ORS 689.205
Hist.: BP 3-2003(Temp), f. 12-29-03, cert. ef. 12-31-03 thru 6-28-04; BP 4-2004, f. 5-21-04 cert. ef. 6-1-04; BP 1-2010, f. & cert. ef. 2-8-10

Supervising Physician Dispensing Outlets

855-043-0405
Purpose and Scope

A supervising physician or supervising physician organization that supervises a physician assistant with dispensing authority must register the dispensing site with the Board as a Supervising Physician Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0410
Registration

(1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.

(2) The initial application must state the location of the SPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant’s affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation’s officers.

(3) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(4) An initial application must be accompanied by the fee established in division 110 of this chapter.

(5) A certificate of registration will be issued upon Board approval of the application.

(6) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.

(7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.

(8) The registration is not transferable and the registration fee cannot be prorated.

(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.

(10) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0415
Consulting Pharmacist

(1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.

(2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed inspection report form must be filed in the outlet, retained on file for three years and be available to the Board for inspection.

(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization. The consulting pharmacist must:

(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and

(b) Work in consultation with the supervising physician in the development of the formulary of drugs and classes of drugs for the outlet.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0420
Policies and Procedures

The registered SPDO must:

(1) Maintain written policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping and accountability;

(2) Maintain all drug records required by federal and state law;

(3) Establish procedures for procurement of drugs; and

(4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued competence of physician assistants who dispense drugs.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0425
Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the public.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0430
Storage of Drugs

All drugs, including drug samples, must be stored under conditions that ensure proper sanitation, temperature, light, ventilation, moisture control, and any other condition recommended by the manufacturer.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0435
Labeling

(1) A prescription must be labeled with the following information:

(a) Unique identifier;

(b) Name of patient;

(c) Name of prescriber;

(d) Name, address, and phone number of the clinic;

(e) Date of dispensing;

(f) 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;

(g) Quantity dispensed;

(h) Directions for use;

(i) Initials of the physician assistant or practitioner dispensing;

(j) Cautionary statements, if any, as required by law; and

(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and

(l) 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.

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0440
Dispensing and Drug Delivery

(1) Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must be personally dispensed by the practitioner or physician assistant.

(2) Prior to dispensing a medication a drug utilization review must be performed by the physician assistant or practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.

(3) The physician assistant or practitioner must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.

(4) When dispensed, a drug must be accompanied by written information that contains at least the following information:

(a) Drug name, class and indications;

(b) Proper use and storage;

(c) Common side effects;

(d) Precautions and contraindications; and

(e) Significant drug interactions.

(5) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient’s agent when the product is dispensed, unless an exemption applies.

(6) Any other requirement of State or federal law.

(7) A SPDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.

(8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.

(9) A SPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(10) The most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0445
Drug Dispensing Training Program

A physician assistant must complete a drug dispensing training program jointly developed by the Oregon Medical Board and the Board of Pharmacy before dispensing drugs to patients.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0450
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

855-043-0455
Record Keeping

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

(a) Name of patient;

(b) Unique identifier;

(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(d) Directions for use;

(e) Date of dispensing; and

(f) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(3) Records documenting training required by OAR 855-043-0445 must be kept for three years.

(4) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 2012 OL Ch 34
Hist.: BP 3-2012, f. & cert. ef. 6-19-12

Correctional Facilities

855-043-0600
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; Renumbered from 855-041-0170, BP 7-2012, f. & cert. ef. 12-17-12

855-043-0610
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; Renumbered from 855-041-0173, BP 7-2012, f. & cert. ef. 12-17-12

855-043-0620
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; Renumbered from 855-041-0175, BP 7-2012, f. & cert. ef. 12-17-12

855-043-0630
Drug Delivery and Control

(1) Policies and Procedures: The pharmacist and the practitioner representing the facility shall be responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures shall be reviewed and updated annually by the pharmacist and the practitioner, maintained in the facility; and be made available to the Board for inspection. The facility shall submit to the Board for approval, the name of any employee pharmacist or a written agreement between the pharmacist and the facility regarding drug policies and procedures. The facility shall notify the Board of any change of pharmacist within 15 days of the change.

(2) Dispensing: Prescription drugs shall be dispensed by a pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system.

(3) Unit Dose Dispensing System. The “Unit Dose Dispensing System” is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:

(a) A unit dose dispensing system shall:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

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

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

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

(ii) Record the actual doses dispensed and returned to the pharmacy;

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

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

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

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

(b) Each correctional facility utilizing a unit dose dispensing system shall establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies shall be available in the pharmacy for inspection by the Board:

(A) Proper utilization of the unit dose system requires that, in as far as is practicable, all medications be in unit dose packaging when dispensed.

(B) Controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with OAR 855-041-0177(4).

(c) The pharmacist shall certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication shall be stored in a locked area or locked cart.

(4) Labeling: Prescription drugs dispensed in individual containers or medication cards shall be labeled with the following information:

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the pharmacist of the patient's record, the pharmacist shall initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent pharmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it shall include information that a reasonable and prudent pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

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

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

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

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

(d) Subsections (a) and (b) of this section shall not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a pharmacist is not required to provide oral counseling when a patient refuses the pharmacist's attempt to counsel, or when the pharmacist, on

a case by case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.

(f) Board rules for patient counseling must be observed for patient/inmates who self administer or who are given prescription drugs when they are released from the correctional facility.

(6) Administration: Drugs shall be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined in Nursing Board administrative rule 851-047-0020. Drugs selected by registered nurses from manufacturer's or pharmacist's bulk drug containers shall not be administered by unlicensed persons, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

Stat. Auth. : ORS 689.205
Stats. Implemented: ORS 689
Hist. PB 1-1996, f. & cert. ef. 4-5-96; Administrative correction 11-3-99; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; Renumbered from 855-041-0177, BP 7-2012, f. & cert. ef. 12-17-12

Community Health Clinic Drug Outlet

855-043-0700
Purpose and Scope

(1) The purpose of 855-043-0700 to 855-043-0750 is to provide minimum requirements of operation for a Community Health Clinic (CHC) to utilize a Registered Nurse to dispense medications. A Community Health Clinic Drug Outlet registration replaces a Family Planning or County Health Drug Outlet registration. A legend or non-prescription drug may be dispensed to a client for the purpose of birth control, caries prevention, the treatment of amenorrhea, the treatment of a communicable disease, hormone deficiencies, urinary tract infections or sexually transmitted diseases by a practitioner who has been given dispensing privileges by their licensing Board, or a Registered Nurse, who is an employee of a clinic or local public health authority (LPHA), and is recognized by the Oregon Public Health Division for the purposes of providing public health services.

(2) Dispensing must be pursuant to the order or prescription of a person authorized by their Board to prescribe a drug or established by the Medical Director or clinic practitioner with prescriptive and dispensing authority.

(3) Family Planning or County Health Clinic registrations that expire March 31, 2017 will be converted to the CHC category upon renewal in 2017. However, rules take effect on July 1, 2016.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0705
Registration

(1) A Community Health Clinic Drug Outlet must register with the Board on a form prescribed by the Board, and must renew its registration annually on a renewal form prescribed by the Board.

(2) An initial application and renewal application must be accompanied by the fee established in division 110 of this Chapter.

(3) A certificate of registration will be issued upon Board approval of the application.

(4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this Chapter with the renewal application.

(5) The registration is not transferable and the registration fee cannot be prorated.

(6) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. A substantial change shall include but not be limited to: a change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or Medical Director.

(7) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this Chapter within 15 days of the change.

(8) A CHC Drug Outlet may be inspected by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0710
Personnel

(1) A Community Health Clinic Drug Outlet must employ a Medical Director who is an Oregon practitioner with prescriptive and dispensing authority. The Medical Director shall establish and enforce policies and procedures, drug dispensing formulary, and protocols for the dispensing of drugs by authorized persons in the CHC.

(2) A CHC Drug Outlet must designate a representative employee who will act as the contact person for the Oregon Board of Pharmacy. The designated representative must be onsite the majority of the CHC's normal operating hours.

(a) The Medical Director or designated representative must conduct and document an annual review of the outlet on a form provided by the Board. The completed report must be filed in the outlet, retained on file for three years and be available to the Board for inspection.

(b) The Medical Director shall develop policies and procedures for the outlet in collaboration with the designated representative.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

Policies and Procedures

855-043-0715
Policies and Procedures
The Community Health Clinic must:

(1) Maintain written policies and procedures for drug management, including security, acquisition, storage, dispensing and drug delivery, disposal, and record keeping.

(2) Establish procedures to train a Registered Nurse employed by the CHC to ensure continued competence in the dispensing of drugs.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0720
Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) Only a Physician, Clinical Nurse Specialist, Nurse Practitioner, or Registered Nurse shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0725
Drug Acquisition

The CHC must verify that all drugs are acquired from a registrant of the Board.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0730
Storage of Drugs

All drugs, including drug samples, must be stored according to the manufacturer's published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0735
Labeling

(1) A prescription must be labeled with the following information:

(a) Unique identifier (i.e. prescription number);

(b) Name of patient;

(c) Name of prescriber;

(d) Name, address, and phone number of the clinic;

(e) Date of dispensing;

(f) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(g) Quantity dispensed;

(h) Directions for use;

(i) Initials of the practitioner who has been given dispensing privileges by their licensing Board or the Registered Nurse;

(j) Cautionary statements, if any, as required by law; and

(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0740
Dispensing and Drug Delivery

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) All drugs must be dispensed in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.

(7) Drugs must be repackaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the Board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0745
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-043-0750
Record Keeping

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

(a) Name of patient;

(b) Unique identifier (i.e. prescription number);

(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(d) Directions for use;

(e) Date of dispensing; and

(f) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305
Hist.: BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

BOARD OF PHARMACY

DIVISION 44
CHARITABLE PHARMACIES

855-044-0001
Purpose

The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept donated drugs for distribution when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0005
Definitions

(1) “Charitable Pharmacy” means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.

(2) “Point-of-Contact” means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0010
Registration

(1) A facility may not operate as a charitable pharmacy unless it is registered as such with the Board and has paid the fee specified in Division 110 of these rules.

(2) The application for registration must be on a form provided by the Board and must include proposed policies and procedures and a description of the organization.

(3) Each location must be registered separately.

(4) An applicant for registration as a charitable pharmacy must name a point-of-contact for each registered location.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0020
Personnel

(1) A charitable pharmacy must have a licensed pharmacist. The pharmacist may also be the Point-of-Contact.

(2) A charitable pharmacy that is co-located with an existing registered pharmacy may name a pharmacist employed by the existing pharmacy as its pharmacist.

(3) A charitable pharmacy that is not co-located with an existing registered pharmacy and does not have a pharmacist on staff must employ a consultant pharmacist.

(4) The pharmacist must develop policies and procedures for:

(a) Receiving donated drugs;

(b) Security;

(c) Drug storage;

(d) Distribution of drugs;

(e) Record keeping;

(f) Disposal of unusable drugs; and

(g) Staff training.

(5) The pharmacist must conduct a visual inspection of each donated drug to ensure that the drug has not expired, been adulterated or misbranded and is in its original, sealed packaging, and that based on this inspection and on the accuracy of the Donor's Form, the drug is safe to distribute.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0030
Drug Donation

(1) A charitable pharmacy may not accept:

(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;

(b) A non-prescription drug;

(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL.

(2) A charitable pharmacy may accept:

(a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3) The following are examples of acceptable packaging:

(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0040
Storage and Security

(1) A charitable pharmacy must store all donated drugs securely and physically separate from any existing inventory.

(2) All charitable pharmacy records must be secured to comply with HIPAA and all state and federal regulations.

(3) Outdated and unusable drugs intended for destruction must be quarantined and stored securely.

(4) A charitable pharmacy co-located with an existing pharmacy must use storage and record keeping procedures that maintain separation of charitable pharmacy records and drugs from other pharmacy records and inventory.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0050
Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

(b) Has not been stored in accordance with manufacturer's recommendations;

(c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;

(d) Bears an expiration date that is less than nine months from the date the drug is donated;

(e) Is adulterated or misbranded;

(f) Is a controlled substance;

(g) Is a drug that requires a special registration for dispensing;

(h) Is an over-the-counter drug;

(i) Requires specialty storage or handling;

(j) Requires refrigeration;

(k) Is a compounded drug; or

(L) In the pharmacist's professional judgment, may be unfit for dispensing.

(2) A charitable pharmacy may only dispense a drug to a person who:

(a) Has a valid prescription for the drug; and

(b) Is a resident of Oregon; and

(c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or

(d) Is enrolled in a program of public assistance as defined in ORS 411.010;

(3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:

(a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and

(b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.

(4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

(a) The prescription drug was donated to the program;

(b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;

(c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;

(d) Participants in the program are immune from liability as provided in ORS 689.780; and

(e) That they are qualified to receive the drug as specified in section (2) of this rule.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0060
Labeling

(1) The label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:

(a) The name, address and telephone number of the pharmacy;

(b) The name of the prescribing practitioner;

(c) The initials of the dispensing practitioner;

(d) Date dispensed;

(e) The name of the patient;

(f) Name and manufacturer of drug, drug strength, the quantity dispensed;

(g) Direction for use;

(i) The expiration date;

(j) A unique identifier; and

(k) Any further cautionary information required for patient safety.

(2) All original patient identification must be removed.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0070
Records

(1) A charitable pharmacy must maintain a donation record of all drugs received that includes:

(a) Donor's name and address;

(b) Drug manufacturer, lot number, name and strength;

(c) Drug quantity;

(d) Expiration date of the drug;

(e) Date donated; and

(f) The unique identifier.

(2) A charitable pharmacy must maintain a distribution and dispensing record that includes:

(a) Drug name and strength;

(b) Quantity distributed;

(c) Name of manufacturer;

(d) Lot number and expiration date;

(e) Date of distribution or dispensing;

(f) Name and address of recipient.

(3) A charitable pharmacy must maintain a record of all drugs that are destroyed.

(4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.

(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board and submitting it with their application for renewal of registration.

(6) All records required by these rules must be retained for three years and made available to the Board upon request.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10; BP 9-2014, f. & cert. ef. 12-4-14

855-044-0080
Fees

(1) A charitable pharmacy may not charge a fee for accepting a donation.

(2) A charitable pharmacy may not sell a donated drug.

(3) A charitable pharmacy may charge a dispensing fee that does not exceed two and a half times Oregon’s current Medicaid dispensing fee.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0090
Liability

In accordance with ORS 689.780, a person who accepts or distributes donated prescription drugs through the charitable pharmacy program is not subject to criminal prosecution or civil liability for any injury, death or loss of or damage to person or property that results from the acceptance or distribution of the donated prescription drugs if the participant accepts or distributes the donated prescription drugs in good faith.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774 & 689.780
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

BOARD OF PHARMACY

DIVISION 45
STERILE AND NON-STERILE COMPOUNDING

855-045-0200
Application

(1) These rules (OAR 855-045-0200 to 855-045-0270) apply to any person, including any business entity, located in Oregon that engages in the practice of compounding drugs, or any person, including any business entity, located in any other state that compounds drugs for the use of patients located in Oregon. Compounding of radiopharmaceuticals is specifically exempted from these rules where these rules are in conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the Radiation Protection Services of the Oregon Department of Human Services or any other applicable agency. Any person located outside Oregon that compounds drugs for the use of patients located in Oregon is expected to follow the compounding rules of their home state or these rules, whichever are more stringent.

(2) These rules apply to sterile and non-sterile compounding of medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner - patient relationship.

(3) Whilst the Board does not insist on rigid application of, or adherence to, all the guidelines of the current edition of the United States Pharmacopeia Chapters 795 (USP 795) and 797 (USP 797), it expects pharmacists engaging in compounding to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit of USP 795 and USP 797.

(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with OAR 855-060-0001, with the following exceptions:

(a) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-0005;

(b) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a routine, regularly observed pattern;

(c) Notwithstanding any other provisions of this rule, the preparation of a patient specific product utilizing all non-sterile commercial components, as defined in these rules as Category 1 compounding, is not considered compounding under these rules provided that:

(A) Preparation of these products is an infrequent occurrence;

(B) Quantity of product prepared does not exceed the requirements of a single prescription except that small quantities can be prepared upon request for in-office use by licensed practitioners.

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

855-045-0210
Definitions

As used in this division of administrative rules:

(1) "Airborne Particulate Cleanliness Classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). The levels used in these rules are:

(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air.

(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air.

(c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.

(2) "Beyond Use Date" (BUD) means the date after which the preparation may not be dispensed or administered to a patient. BUD has the same meaning as "Expiration Date".

(3) "Biological Safety Cabinet" (BSC) means a ventilated cabinet with an inward airflow for personnel protection, a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection, and a HEPA filtered exhaust system for environmental protection.

(4) Categories of compounding: In these rules, compounding is defined as:

(a) Category 1: Nonsterile -- Simple: Generally, the mixing of two or more commercial products. In these rules, this is not considered to be compounding.

(b) Category 2: Nonsterile -- Complex: Generally, compounding with bulk drug substances or when calculations are required.

(c) Category 3: Sterile -- Risk Level 1: Low-Risk, as defined in OAR 855-045-0250.

(d) Category 4: Sterile -- Risk Level II: Medium-Risk, as defined in OAR 855-045-0250.

(e) Category 5: Sterile -- Risk Level III: High-Risk, as defined in OAR 855-045-0250.

(5) "Compounding Aseptic Isolator" (CAI) means a glove box isolator with a microbially retentive HEPA air filter that maintains an aseptic compounding environment within the isolator throughout the compounding and material transfer process.

(6) "Compounded Sterile Preparation" (CSP) means:

(a) A preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in IV rooms; or

(b) A preparation containing nonsterile ingredients, or employing nonsterile components and devices, that must be sterilized before administration; or

(c) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injections, irrigations, metered sprays, and ophthalmic and otic preparations.

(7) "Compounding pharmacy" means any pharmacy where sterile or non-sterile compounding occurs on a regular basis.

(8) "Parenteral Admixture" means a sterile preparation that is the combination of one or more sterile products with an appropriate admixture vehicle.

(9) "Laminar Airflow Hood" (LAF) means a workspace where the work surface is subjected to a constant, HEPA filtered airflow that is directed towards the user.

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

855-045-0220
Personnel

(1) Personnel who prepare compounded pharmaceuticals, both sterile and non-sterile, shall be provided with appropriate training before they begin to prepare such products including for CSPs, training in the theoretical principles and practical skills of aseptic manipulations.

(2) The pharmacist in charge (PIC) shall establish pharmacy Policies and Procedures that contain protocols in accordance with the guidelines in USP 797, for the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low and medium risk compounding.

(3) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually.

(4) The PIC shall ensure that training protocols are followed and records are kept for the training of all new personnel and for all continuing education and periodic testing that is completed.

(5) The PIC is responsible for the procedures and the overall operation of all activities within the pharmacy and must:

(a) Ensure all pharmacy personnel involved in preparing compounded products are trained and have demonstrated skills commensurate with the complexity of the procedures they are performing;

(b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accomplished by a review of each compounded product that includes but is not limited to:

(A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient;

(B) Verifying that the correct drugs and components were selected;

(C) Confirming that the calculation and quantity of each drug and component is correct;

(D) Verifying the label is correct and where appropriate contains all the information specified in OAR 855-041-0065 and these rules.

(c) Document verification by the pharmacist responsible for the review.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2011, f. & cert. ef. 4-18-11

855-045-0230
General Requirements

A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has the duty to exercise that degree of care, skill, diligence and professional judgment that is used by ordinarily competent, careful pharmacists in the same or similar circumstances in the community of the pharmacist or a similar community.

(1) A pharmacist engaged in compounding shall:

(a) Conform to all relevant federal laws and rules;

(b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0200(4), and only when, in their professional judgment, it results from a valid prescriber-patient relationship;

(c) Compound only products that are not commercially available except as allowed in OAR 855-045-0240(2), and, except that with the prior approval of the Board, a commercial product that is temporarily in short supply or otherwise unavailable, may be compounded subject to OAR 855-045-0200(4)(c);

(d) Maintain all records in accordance with OAR 855-045-0270;

(e) Perform final product verification.

(2) The pharmacist-in-charge of a compounding pharmacy including a pharmacy that only prepares sterile parenteral products shall ensure that policies and procedures for that pharmacy are reviewed not less than annually, are available for all staff to refer to, and are complied with by all staff. The policies and procedures for a compounding pharmacy shall include but are not limited to, the following:

(a) An organized index;

(b) Product formula information;

(c) Specifications for a compounding log book in compliance with OAR 855-045-0270;

(d) Conditions and surveillance of the compounding environment;

(e) Compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks;

(f) Cleaning and equipment maintenance procedures;

(g) QA plan and documentation;

(h) Shipping and delivery procedures;

(I) Product labeling;

(j) Procedures for final product verification by the pharmacist;

(k) Compounded product quality procedures including procedures for establishing BUD;

(l) Training requirements for all staff;

(m) Safety procedures and training for personnel handling hazardous materials including:

(A) Use of personal protective equipment;

(B) Availability of Manufacturers' Safety Data Sheets;

(C) Emergency procedures related to spills, fire, or exposure to hazardous materials.

(n) Requirements for availability of reference materials.

(3) Pharmacies that compound sterile products including parenteral products shall, when appropriate, also include in their policies and procedures:

(a) Establishment of BUD;

(b) End Product Testing;

(c) Random sampling of both the environment and CSPs.

(4) The pharmacist-in-charge of a compounding pharmacy shall ensure that a quality assurance plan is written for that pharmacy and that:

(a) It includes record keeping requirements for cleaning, testing and calibration of all equipment and devices;

(b) Pharmacies that compound sterile products shall additionally include:

(A) Schedules and protocols for End Product Testing. Pharmacies mixing High Risk Level CSPs or extending Beyond Use Dating (BUD), must establish an End Product Testing schedule that includes random sampling. End Product Testing of a mixing process must show an acceptable sampling of the total preparations prepared annually;

(B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless a quality assurance program is established that verifies End Product Testing beyond the dating established by USP 797. Records to verify sterility and pyrogenicity must be maintained and available for review for three years.

(5) Bulk chemicals require a certificate of analysis.

(6) The labeling of bulk chemical containers shall contain:

(a) The date obtained;

(b) The BUD, which shall be established as specified in the pharmacy policies and procedures but not more than five years after opening unless additional testing is conducted to extend that BUD by not more than one year.

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

855-045-0240
Sterile Parenteral Products

(1) In addition to complying with all the other rules in this chapter of rules that are appropriate to their practice setting, pharmacists compounding sterile parenteral products must comply with the following specific rules.

(a) Establish, maintain and enforce written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy. These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the practice setting and:

(A) Requirements for compounding, labeling and storage of the products;

(B) Requirements for administration of parenteral therapy;

(C) Requirements for storage and maintenance of equipment and supplies.

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

(A) Rate of infusion, as appropriate;

(B) Beyond Use Date;

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

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

(E) Initials of the pharmacist who verified the accuracy of the completed product.

(c) Patient Care Services: Counseling shall be available to the patient or patient's agent concerning proper use of parenterals and related supplies furnished by the pharmacy.

(2) In addition to complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may:

(a) Prepare multiple source commercially available premixed parenteral admixtures;

(b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral solution are commercially available;

(c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture that was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs;

(d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place.

Stat. Auth.: ORS 689.205
Stats Implemented: ORS 689.155
Hist.: PB 5-1987, f. & ef. 5-1-87; PB 12-1989, f. & cert. ef. 8-11-89; BP 7-2005, f. 12-14-05, cert. ef. 12-15-05; Renumbered from 855-041-0063, BP 2-2008, f. & cert. ef. 2-20-08; BP 3-2011, f. & cert. ef. 4-18-11

855-045-0250
Definitions of Risk Levels for Sterile Preparations

The three risk levels of CSPs recognized by USP 797 are based on the probability of contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels are defined, and products must be prepared and managed as follows:

(1) Low Risk Conditions:

(a) CSPs prepared using aseptic manipulation within an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components and devices;

(b) No more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;

(c) Manipulations limited to:

(A) Aseptically opening ampoules;

(B) Penetrating sterile stoppers on vials with sterile needles and syringes;

(C) Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing.

(d) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 48 hours at controlled room temperature;

(B) BUD up to14 days: under refrigeration;

(C) BUD up to 45 days: in solid frozen state at -20 °C.

(2) Medium Risk Conditions:

(a) CSPs compounded aseptically under Low-Risk Conditions but with the addition of one or more of the following conditions:

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;

(B) The compounding process includes complex aseptic manipulations other than single-volume transfer;

(C) The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.

(b) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 30 hours: at controlled room temperature;

(B) BUD up to 9 days: under refrigeration;

(C) BUD up to 45 days: in solid frozen state at -20 °C.

(3) High Risk Conditions:

(a) CSPs compounded from non-sterile ingredients, including products manufactured for other routes of administration, or a non-sterile device is employed before terminal sterilization;

(b) Exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:

(A) Sterile contents of commercially manufactured products;

(B) CSPs that lack effective antimicrobial preservatives;

(C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs.

(c) Prior to terminal sterilization:

(A) Nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;

(B) Compounding personnel are improperly gloved or garbed;

(C) Water-containing preparations are stored for more than 6 hours.

(d) In the absence of sterility testing:

(A) A preparation must be properly stored prior to administration as follows:

(i) For a BUD not to exceed 24 hours, at controlled room temperature;

(ii) For a BUD up to three days, under refrigeration;

(iii) For a BUD up to 45 days, in solid frozen state at -20 °C.

(B) All nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water then thoroughly drained or dried immediately before use;

(C) Terminal sterilization is required as follows:

(i) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter;

(ii) Sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron porosity filter entirely within an air quality environment better than or equal to ISO 5.

(4) Immediate-use:

(a) A compounded preparation intended for immediate use may be prepared in an air quality environment that does not meet ISO 5 or better conditions and a preparer is not required to wear gloves or gown, provided that it is prepared using aseptic manipulation, only sterile ingredients, products, components and devices are used, and it meets all of the following conditions:

(A) No more than three sterile ingredients, products, components and devices are used;

(B) Only simple manipulation techniques employed;

(C) The preparer completes the preparation without interruption and with no direct contact contamination;

(D) Administration must begin within one hour of preparation;

(E) If prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour BUD.

(b) Provided that such preparations do not involve the use of hazardous materials, they are classified as "Low Risk".

(5) "Same-day-use": In this rule, the term "Same-day-use" means that the administration of the preparation shall commence within 24 hours from the time of preparation. A same-day-use product that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile, ingredients, products, components and devices, may be classified as Low or Medium risk provided that it meets all the following conditions:

(A) Only simple manipulation techniques employed;

(B) The environment meets or exceeds the following conditions:

(i) The mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;

(ii) There is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet;

(iii) The buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process;

(iv) The environment is cleaned daily.

(C) The preparer completes the preparation without interruption and with no direct contact contamination;

(D) Batch preparation will not exceed eight CSPs;

(E) Administration of the preparation must begin within twenty-four hours of preparation;

(F) The preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown and mask.

(6) Single-dose vial.

(a) The BUD shall be no greater than one hour from time of initial entry if accessed in an environment worse than ISO 5;

(b) The BUD may be up to 24 hours from time of initial entry if appropriately stored and accessed only in an environment better than or equal to ISO 5;

(c) Medications in a single dose ampoule may not be reused.

(7) Multi-dose vial. The BUD may be up to one month or the manufacturer's assigned BUD whichever is shorter, from time of initial entry, in accordance with the pharmacy policies and procedures.

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

855-045-0260
Pharmacies and Equipment

Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared.

(1) Pharmacies and equipment for the preparation of immediate-use CSPs shall be in accordance with OAR 855-045-0250(4).

(2) Effective January 1, 2009, for preparation of low-risk level CSPs, an ISO 5 certified or better Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CAI), or a Laminar Airflow Hood (LAF) shall be used.

(3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. These areas must have positive airflow unless used to prepare hazardous drugs. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.

(4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a positive air pressure of 0.02 to 0.05-inch water column and may not contain a sink or drain. Surfaces and essential furniture in buffer rooms and zones and anterooms shall be nonporous, smooth, nonshedding, impermeable, cleanable and resistant to disinfectants. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.

(5) Hazardous drugs must be prepared in compliance with state and federal regulations.

(6) Radiopharmaceuticals must be prepared in accordance with OAR 855-042-0005 through 0025.

(7) Pharmacy policies and procedures must include protocols for cleaning and monitoring that include:

(a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be performed at least daily. Floors in ISO 7 and 8 areas cleaned at least daily. Surfaces that are used to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant. Empty shelving, walls and ceilings in anterooms and buffer rooms will be cleaned at least monthly with appropriate disinfectant solution;

(b) All ISO classified areas will be checked and certified by a qualified individual no less than every 6 months and whenever the LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered;

(c) Maintenance, and documentation of maintenance, of all equipment in accordance with manufacturer's specifications.

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

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

855-045-0270
Records

(1) Except for products prepared subject to OAR 855-045-0200(4)(c), all appropriate compounding logs, formula worksheets and documentation of the preparation, verification, dispensing or transfer of all compounded products must be stored in an organized manner, retained for a minimum of three years and be available for inspection by the Board.

(2) The formula worksheets for compounding pharmacies, excluding those for patient specific IV admixture products, must include but are not limited to the following:

(a) Drug name and strength;

(b) Quantity prepared;

(c) Date prepared;

(d) Pharmacy unique lot number;

(e) Manufacturers' lot numbers and expiration dates of all ingredients used to prepare compounded product;

(f) Beyond Use Date;

(g) Name of verifying pharmacist;

(h) Names of all technicians involved in the process;

(I) Copy of the label used for the compounded product;

(j) Mixing instructions;

(k) Physical evidence of the proper weight of each dry chemical or drug used;

(l) Pharmacist verification that the correct formula and the correct weights or volumes of chemical or drugs were used;

(m) Certification of completion of any additional testing, including endotoxin, required by the pharmacy's policies and procedures;

(n) Any other information required by the pharmacy's policies and procedures.

(3) Record of maintenance and certifications for all equipment must be retained for a minimum of three years and be available for inspection by the Board.

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

BOARD OF PHARMACY

DIVISION 50
RESTRICTION ON RETAIL SALES

855-050-0035
Over-the-Counter Drug Restrictions

(1) The following items shall be sold only by or under the direct supervision of a licensed pharmacist in registered pharmacies. They need not bear the store name and address, if in original container, need not be registered, but must be properly labeled. They shall not be available by self-service, but stored in or immediately adjacent to the prescription department. Items bearing prescription legend are excepted and may be sold only on prescription:

(a) Ammoniated Mercury ointment, five percent;

(b) Sulfa drugs -- Alone or in combination;

(c) Blue Ointment.

(2) The following items shall be sold only by a licensed pharmacist(s) in registered pharmacies, must bear the store name and address, must be properly labeled with adequate warning, must be registered in Official Poison Register, and the purchaser must provide acceptable identification, providing the preparations do not bear prescription legend, in which case they may be sold only on prescription:

(a) Arsenic and its preparations;

(b) Corrosive sublimate;

(c) Cyanides and preparations, including hydrocyanic acid;

(d) Hydrochloric acid and any preparation containing free or chemically unneutralized hydrochloric acid (HC1) in a concentration of ten percent or more;

(e) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO_3) in a concentration of five percent or more;

(f) Sulphuric acid and any preparation containing free or chemically unneutralized sulphuric acid (H_2S0_4) in a concentration of ten percent or more;

(g) Solution of ammonia, U.S.P. 28 percent;

(h) Carbolic acid.

Stat. Auth.: ORS 689
Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 2-1979(Temp), f. & ef 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 4-1988, f. & cert. ef. 7-5-88; BP 6-2004(Temp), f. 10-15-04 cert. ef. 11-1-04 thru 5-13-05; Administrative correction 5-20-05

855-050-0045
Organic Silver Salts

(1) May be sold only by licensed pharmacists in registered pharmacies.

(2) Solutions must be freshly prepared, unless stabilized.

(3) Must be adequately labeled, to include name and address of store, date of preparation, and percentage content.

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

855-050-0070
Prescription Drugs

(1) The following are prescription drugs:

(a) Drugs required by federal law to be labeled with either of the following statements:

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

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

(C) "Rx only"

(b) Drugs designated as prescription drugs by the Oregon Board of Pharmacy

(2) The Oregon Board of Pharmacy designates the following drugs as prescription drugs:

(a) Preparations containing codeine or salts of codeine

(b) Preparations containing opium/paregoric

(3) No person shall sell, give away, barter, transfer, purchase, receive or possess prescription drugs except upon the prescription of a practitioner.

(4) The following are exempt from the prohibition of section (3) of this rule:

(a) Manufacturers

(b) Wholesalers;

(c) Institutional and retail drug outlets;

(d) Practitioners.

(5) Individuals who purchase, receive, or possess a prescription drug for the purpose of administration or delivery to a patient are exempt from the prohibition against purchasing, receiving, or possessing prescription drugs contained in section (3) of this rule and ORS 689.765(6).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.765
Hist.: PB 3-1990, f. & cert. ef. 4-5-90; PB 9-1990, f. & cert. ef. 12-5-90; PB 4-1991, f. & cert. ef. 9-19-91; BP 1-2002, f. & cert. ef. 1-8-02; BP 7-2004, f. & cert. ef. 11-8-04; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 14-2006(Temp), f. 12-29-06, cert. ef. 1-1-07 thru 6-29-07; BP 1-2007, f. & cert. ef. 6-29-07

BOARD OF PHARMACY

DIVISION 60
PHARMACEUTICAL MANUFACTURERS

855-060-0001
Application

No place of manufacturing, wholesaling or repackaging of drugs or medicines, as defined in ORS 689.005(20), (35), and (36) shall be conducted or operated until it has been registered by the State Board of Pharmacy, except that compounding or repackaging, as a part of a Shared Pharmacy Services agreement as defined in OAR 855-006-0005(20), does not constitute manufacturing. Manufacturing registration expires September 30th annually:

(1) All applications for registration of a new or relocated manufacturer shall be accompanied by the required fees as set forth in 855-110-0007(3).

(2) Application shall specify the location of the manufacturer premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner;

(a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the five largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(c) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(3) All registration renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (2)(a), (b), and (c) of this rule.

(4) A change of ownership or location requires a new application, fee and registration within 15 days.
(5) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(6) The registration cannot be prorated.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 689.315 & 689.325
Hist.: 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94; Administrative correction 5-23-00; BP 1-2002, f. & cert. ef. 1-8-02; BP 12-2006, f. & cert. ef. 12-19-06

855-060-0002
Definitions

(1) “Affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

(2) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(3) “Illegitimate Product” means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

(4) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(5)"Pedigree" for the purpose of this Division consists of:

(a) “Transaction History” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information” must include but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (FDA) regulations set forth by the Drug Quality and Security Act and includes but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(6) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 4-2015, f. & cert. ef. 7-1-15

855-060-0004
Registration

(1) Any person that manufactures, or contracts for the manufacture of a drug or prescription device that is intended for sale, distribution, dispensing or administration in Oregon must register with the Oregon Board of Pharmacy.

(2) Any person that holds one or more of the following registrations with the Food and Drug Administration (FDA) must register as a Manufacturer.

(a) A New Drug Application number (NDA);

(b) An Abbreviated New Drug Application number (ANDA);

(c) A Labeler Code number (LC) or National Drug Code number (NDC);

(d) An FDA Central File Number (CFN);

(e) An FDA Establishment Identifier number (FEI);

(f) A Biologic License Application (BLA);

(g) An Outsourcing Facility Registration.

(3) A person that is registered with the FDA as a repackager must register as a Manufacturer.

(4) A person who is a third-party logistics provider as defined in Division 62 or whose sole purpose is the marketing, brokering or arranging the initial distribution of drugs manufactured by a manufacturer must register as a Drug Distribution Agent under Division 62.

(5) A person who is registered with the FDA as the agent for a foreign manufacturer must register as a Drug Distribution Agent under Division 62.

(6) An applicant for a new or renewal of registration must provide all information specified on the form provided by the Board, and pay the fee as specified in OAR 855-110-0007. The applicant must also provide any additional information requested by the Board. An application that does not contain all required information is incomplete and will not be processed.

(7) The registration is non-transferable. Addition or deletion of an owner shall be considered as a change of ownership except where the registrant is a publicly held corporation. A new application for registration and payment of a new registration fee is required when a registrant changes ownership or location. This new application must be submitted to the Board at least 15 days prior to the change.

(8) A person who compounds a drug that is distributed in Oregon not based on a patient specific prescription must register with the Board as a Manufacturer, unless done so pursuant to a Shared Pharmacy Services agreement, as defined in OAR 855-006-0005, between two in-state entities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.305
Hist.: BP 9-2011, f. 12-30-11, cert. ef. 1-1-12; BP 1-2013(Temp), f. 3-6-13, cert. ef. 3-7-13 thru 9-3-13; BP 5-2013, f. & cert. ef. 8-29-13; BP 4-2015, f. & cert. ef. 7-1-15

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 and must comply with 503B manufacturing requirements of 21 USC 353 and is exempted from labeling and research requirements.

(3) Class III. Repackagers or distributors of non-legend drugs will not be required to have a licensed pharmacist but is required to have competent supervisory personnel.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
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; BP 4-2015, f. & cert. ef. 7-1-15

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, 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 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;

(b) Drug products which are used for experimentation or research purposes.

(4) The Board of Pharmacy, upon application of a manufacturer or distributor, may also exempt a particular drug product from the requirements of this regulation on the grounds that imprinting is not feasible because of such drug product's size, texture, or other unique characteristics.

Stat. Auth.: ORS 475 & 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1981, f. & ef. 8-20-81; BP 4-2015, f. & cert. ef. 7-1-15

855-060-0029
Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or illegitimate shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Stat. Auth.: ORS 475.035, 689.155, 689.205, 689.305 & 689.315
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1992, f. & cert. ef. 1-31-92; BP 4-2015, f. & cert. ef. 7-1-15

855-060-0035
Registration of Mobile Manufacturers

(1) A mobile manufacturer means a manufacturer who manufactures within a vehicle equipped to provide unit dose packaging and repackage capabilities operated by a currently licensed pharmacist in this state.

(2) Stock medication for packaging and repacking will be furnished by the purchaser and shall exclude controlled substances.

(3) The vehicle shall be secure against pilferage, maintained and operated in accordance with good manufacturing practices standards in this division.

(4) All unit dose packages must be labeled in conformity with ORS 689.005.

(5) Records shall be maintained of all package operations of receipt and disposition of drugs.

(6) The building in which this vehicle is stored shall be its permanent address and shall maintain security of vehicle.

(7) Vehicle shall be registered annually; registration shall expire annually on July 1, of each year.

(8) Applicant must show to the Board that he will be actively in charge of equipment in this vehicle at all times it is in operation.

(9) If so required, the vehicle shall be registered with the federal Food and Drug Administration.

(10) The vehicle shall not display insignia or device to indicate that drugs are stored within or represent it as a pharmacy.

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

BOARD OF PHARMACY

DIVISION 62
DRUG DISTRIBUTION AGENT

855-062-0003
Application

(1) The following persons must register as a Drug Distribution Agent under this Division of rules:

(a) A broker;

(b) An import broker;

(c) An agent for a foreign manufacturer who is registered with the Food and Drug Administration (FDA);

(d) Sales and marketing office for a drug;

(e) A Drug Order Contractor;

(f) A Third-Party Logistics Provider; and

(g) A person registered with the FDA as the holder of a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) that contracts with a third-party for the manufacture of a drug but does not take physical possession of the drug, does not have its name on the label and is not accountable to the FDA for the purity and integrity of the drug.

(2) Any person who would otherwise be required to register as a Wholesaler under Division 65 of this Chapter of rules but who does not at any time have possession of a drug intended for distribution must register as a Drug Distribution Agent under this Division of rules.

(3) A person whose sole purpose is the marketing, brokering or arranging the initial distribution of drugs manufactured by a registered manufacturer, but does not take physical possession of a product must register as a Drug Distribution Agent.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 4-2015, f. & cert. ef. 7-1-15

855-062-0005
Definitions

(1) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the drug.

(2) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(3) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(4)"Common Carrier" means an organization that is available to the public to transport a product or service using its facilities, or those of other carriers.

(5) “Drug”: In this Division of rules, the term “drug” shall mean any drug and any prescription device as these terms are defined in ORS 689.005.

(6) “Illegitimate Product” means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

(7) “Manufacturer” means any person, including a manufacturer's co-manufacturing partner, that is engaged in the manufacture of a drug, is responsible or otherwise accountable to the Food and Drug Administration (FDA) for the manufacture of the drug, or is the private label manufacturer or distributor of product bearing its NDC number that is intended for sale, distribution, dispensing or administration in Oregon, and who holds one or more of the following registrations or licenses with the FDA:

(a) A New Drug Application number (NDA);

(b) An Abbreviated New Drug application number (ANDA);

(c) A Labeler Code number (LC) or National Drug Code Number (NDC);

(d) An FDA Central File Number (CFN);

(e) An FDA Establishment Identifier number (FEI);

(f) A Biologic License Application (BLA);

(g) An Outsourcing Facility.

(8) “Manufacture” means the preparation, propagation, compounding, or processing of a drug or device intended for human or animal use. Manufacture includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(9)"Pedigree" for the purpose of this Division consists of:

(a) “Transaction History” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information” must include, but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with FDA regulations set forth by the Drug Quality and Security Act and includes, but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(10) “Person” means individual, corporation, partnership, association, joint-stock company, business trust or unincorporated organization.

(11) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(12) “Third-Party Logistics Provider” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, and not have responsibility to direct the sale or disposition of the product.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 4-2015, f. & cert. ef. 7-1-15

855-062-0020
Registration

(1) Any person engaged in any part of the process of manufacture or wholesale distribution of a drug into, out of, or within Oregon must be registered with the Board. A person must register as either:

(a) A manufacturer under Division 60 of this chapter of rules; or

(b) A wholesaler under Division 65 of this chapter of rules; or

(c) A Drug Distribution Agent under this division of rules.

(2) A person that is required to register as a Drug Distribution Agent must be registered before commencing business in Oregon and before any drug for which they provide a manufacturing, marketing or distribution service, may be sold, distributed, dispensed or administered in Oregon.

(3) A person that is required to register as a Drug Distribution Agent must apply for registration on a form provided by the Board and must provide information required by the Board that shall include but is not limited to:

(a) The name, business address, social security number or federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) Every trade or business name used by the applicant;

(c) Any disciplinary action taken by any state or federal authority against the applicant or any other distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(4) An applicant for renewal must complete the form provided by the Board and submit it to the Board with the appropriate fee by August 31 annually.

(5) An applicant that provides a manufacturing or distribution service in respect of a controlled substance as defined in Division 80 of this chapter of rules must also complete and submit the Controlled Substance registration form provided by the Board, with the appropriate fee.

(6) The Board may require a criminal history and financial background check of each principal, owner or officer of the applicant prior to initial registration and prior to any renewal unless the applicant is publicly traded. Any such checks shall be at the applicant's expense.

(7) The Board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(8) Each separate business entity and each location that does business in Oregon must be separately registered by the Board.

(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but is not limited to:

(a) Change of ownership;

(b) Change of business address;

(c) Any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers.

(10) The registration certificate is issued to a specific person and is non-transferable. Any addition or deletion of an owner or partner constitutes a change of ownership.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0030
Minimum Qualifications

The Board may deny an application for registration or renewal of registration as a Drug Distribution Agent on any of the following grounds:
(1) The applicant has been found by the Board or by a court to have violated the pharmacy or drug laws or rules of this state or of any other state, or of the federal government;

(2) The applicant has a history of non-compliance with state or federal rules or laws regulating the manufacture, distribution, or dispensing of drugs;
(3) The applicant has made a material misrepresentation to the Board in the course of applying for an initial or renewal of registration;

(4) Disciplinary action has been taken by the federal government or by any state, or local government regarding any license or registration currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs;

(5) The applicant has engaged in any conduct involving moral turpitude;

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-062-0040
Record Keeping

(1) A Drug Distribution Agent must establish and maintain records regarding the distribution or other disposition of a drug.

a) If a Drug Distribution Agent distributes product to a wholesaler or pharmacy, the record must contain, but is not limited to the following:

(A) The source of the drug, including the name and physical address of the seller or transferor and any broker or other person involved in the transaction, the address of the location from which the drug was shipped and the address of the location to which the drug was shipped;

(B) The name, dose and quantity of the drug distributed;

(C) The date of distribution or other disposition of the drug.

(b) If a Drug Distribution Agent distributes product to another Drug Distribution Agent, the pedigree must be maintained and provided to the recipient of the distribution.

(2) Records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, authorized law enforcement agencies, and this Board.

(3) Records required under these rules must be maintained for three years.

(4) Records required under these rules that are less than 13 months old must be kept at the address of record or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by these rules must be made available for inspection within three business days of a request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 5-2015(Temp), f. & cert. ef. 7-1-15 thru 12-27-15; BP 8-2015, f. & cert. ef. 12-23-15

855-062-0050
Prohibited Practices

(1) The following practices are expressly prohibited:

(a) A Drug Distribution Agent may not participate in the purchase of a drug from a closed-door pharmacy;

(b) A Drug Distribution Agent may not participate in any way in the sale, distribution or transfer of a drug to a person who is required by the laws and rules of Oregon to be registered with the Board and who is not appropriately registered. Before authorizing or facilitating the distribution of a drug, a Drug Distribution Agent must verify that the person supplying or receiving the drug is appropriately registered with the Board.

(2) A Drug Distribution Agent may not perform, cause the performance of, or aid the performance of any of the following:

(a) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution;

(b) The adulteration, misbranding, or counterfeiting of a drug;

(c) The receipt of a drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the drug for pay or otherwise;

(d) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a drug or the commission of another act with respect to a drug that results in the drug being misbranded;

(e) The forging, counterfeiting, simulating, or falsely representing a drug using a mark, stamp, tag, label, or other identification device;

(f) The purchase or receipt of a drug from a person that is not registered to distribute drugs to the purchaser or recipient;

(g) The sale or transfer of a drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug, to purchase or receive drugs from the person selling or transferring the drug;

(h) The failure to maintain or provide records as required under these rules;

(i) Providing the Board, a representative of the Board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to these rules;

(j) Participating in the wholesale distribution of a drug that was:

(A) Purchased by a public or private hospital or other health care entity under the terms of an "own-use" contract; or

(B) Donated or supplied at a reduced price to a charitable organization; or

(C) Stolen or obtained by fraud or deceit; or

(D) Illegally imported into the USA.

(k) Facilitating the distribution or attempting to facilitate the distribution of a drug by fraud, deceit, or misrepresentation;

(l) Facilitating the distribution of a drug that was previously dispensed by a retail pharmacy or a practitioner;

(m) Failing to report an act prohibited by any of the rules in OAR Chapter 855 to the appropriate state or federal authorities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 4-2015, f. & cert. ef. 7-1-15

BOARD OF PHARMACY

DIVISION 65
WHOLESALE DRUG OUTLETS

855-065-0001
Application

(1) These rules (OAR 855-065-0001 to 855-065-0013) apply to any person, including any business entity, located in or outside Oregon that engages in the wholesale distribution of prescription or non-prescription drugs in Oregon except that a manufacturer that is registered under division 60 of this chapter of rules does not also need to register as a wholesale distributor under these rules if they only distribute their own products or those manufactured by a Co-Manufacturing Partner as defined in OAR 855-065-0005.

(2) Any person who is a Third-Party Logistics Provider as defined in division 62 or whose sole purpose is the marketing, brokering or arranging the distribution of drugs manufactured by a manufacturer must register as a Drug Distribution Agent in accordance with division 62 of this chapter of rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); PB 1-1994, f. & cert. ef. 2-2-94; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 4-2015, f. & cert. ef. 7-1-15

855-065-0005
Definitions

(1) “Affiliate” means a business entity that has a relationship, or is an authorized trading partner, with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:
(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or
(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.

(3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the brokered substance.

(4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

(5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(7) "Designated Representative" means an individual designated by each wholesale distributor registered by the Board who will serve as the primary contact person for the wholesale distributor with the Board and who is responsible for managing the company's operations at that registered location.

(8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.

(9) “Illegitimate Product” means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

(10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.

(11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(12) "Pedigree" for the purpose of this Division consists of:

(a) “Transaction History,” which means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information,” which must include, but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement,” which is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (FDA) regulations set forth by the Drug Quality and Security Act and includes but is not limited to:
(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;
(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

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

(14) “Quarantine” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

(15) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the product to a patient.

(16) “Repackager” means a person who owns or operates an establishment that repacks and relabels a product or package for:

(a) Further sale; or

(b) Distribution without a further transaction.

(17) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death.

(18) “Trading Partner” means:

(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(19) “Validate” means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

(20) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.
(b) The sale of minimal quantities of a prescription drug by retail or institutional pharmacies to licensed practitioners for office use.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:

(A) Emergency medical reasons;

(B) Drug or devices used during a federal or state declared emergency; or

(C) The transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.

(d) Intra company transfer of drugs as defined in these rules.

(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.

(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit affiliate of the organization to the extent permitted by law.

(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.

(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.

(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.

(j) The sale, purchase, or trade of blood and blood components intended for transfusion.

(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

(l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

(m) The distribution of drugs by a manufacturer registered under division 60 of this chapter of rules of its own products to a person other than a patient.

(21) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors;

retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(22) "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons and is required to comply with all pedigree requirements;

(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any non-prescription drugs are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer.

(c) “Class III Wholesaler” means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:
(A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;

(B) Prescription devices that do not contain a prescription drug;

(C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the Board;

(D) Oxygen USP and medical gases;

(E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or calories;

(F) Medical convenience kits which includes any non controlled drug product or biological product, assembled in kit form.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 4-2012(Temp), f. & cert. ef. 6-19-12 thru 12-16-12; BP 6-2012, f. & cert. ef. 12-13-12; BP 4-2015, f. & cert. ef. 7-1-15

855-065-0006
Registration Requirements

(1) Every wholesale distributor, wherever located, that engages in wholesale distribution into, out of, or within Oregon must be registered with the Board in accordance with the laws and regulations of Oregon before engaging in wholesale distribution of drugs. Every applicant for registration or renewal of registration must pay the appropriate fee in accordance with OAR 855-110-0007 and 855-110-0010. An applicant must register as a Class I Wholesaler or a Class II Wholesaler unless the applicant qualifies for registration as a Drug Distribution Agent under Division 62 of this chapter of rules.

(2) Application for registration must be on a form approved by the Board and must include, but not be limited to, the following information:

(a) The name, business address, social security number and federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) All trade or business names used by the applicant including any businesses outside Oregon;

(c) The names, addresses and telephone numbers of the designated representatives for all facilities used by the applicant that engage in wholesale distribution into, out of, or within Oregon;

(d) The normal business hours for the applicant; and

(e) Any disciplinary action taken by any state or federal authority against the applicant or any other wholesale distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(3) The Board may require a criminal history and financial background check of each principal, owner, officer and designated representative of the applicant prior to initial registration and prior to any renewal. Any such checks shall be at the applicant's expense.

(4) The Board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(5) Any wholesale distributor located outside the boundaries of Oregon, applying for registration or re-registration, as a Class I Wholesaler, must provide evidence of one of the following:

(a) A current license or registration as a wholesale distributor in a state that has a license or registration procedure approved by the Board that included a physical inspection within the past three years; or

(b) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service.

(6) Any wholesale distributor located inside the boundaries of Oregon, applying for registration or re-registration, as a Class I Wholesaler, must provide evidence of one of the following:

(a) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service; or

(b) That it is a small business as defined in ORS 183.310(10); and

(A) The applicant has no affiliation with any out-of-state pharmaceutical company; and

(B) All owners and principals of the applicant are Oregon residents; and

(C) No owner or principal, or close family member of an owner or principal, has a controlling or business interest in any other pharmaceutical company; and

(D) Neither the applicant, nor any of its owners or principals, has ever been found to be in violation of any drug law or regulation in this or any other state.

(7) In addition to the above registration requirements, an applicant for registration as a Class I wholesaler under this rule, that has not received VAWD accreditation, must provide evidence that it has obtained a bond or equivalent means of security of at least $100,000 that provides direct access to the Oregon Board of Pharmacy as a beneficiary to secure payment of any administrative penalties that may be imposed by the Board and any fees and costs that may be incurred by the Board and that:

(a) Are related to a registration held by the wholesale distributor; and

(b) Are authorized under Oregon law; and

(c) The wholesale distributor fails to pay less than thirty days after the penalties, fees, or costs become final.

(8) The Board may make a claim against a bond or security posted under section (7) of this rule within one year after the wholesale distributor's registration is no longer valid or sixty days after the conclusion of whichever occurs later:

(a) An administrative or legal proceeding before or on behalf of the Board that involves the wholesale distributor and results in penalties, fees or costs; or

(b) An appeal of such a proceeding.

(9) Where operations are conducted at more than one location by a single wholesale drug outlet, each such location that does business in Oregon must be registered by the Board.

(10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or designated representatives.

(11) The registration certificate is issued to a specific person and is non-transferable. Additions or deletions of an owner or partner shall be considered as a change of ownership.

(12) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in OAR 855-110-0007 within 15 days of the change.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 12-2006, f. & cert. ef. 12-19-06; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09

855-065-0007
Minimum Qualifications

The Board may deny an application for an initial registration or renewal of registration as a wholesale distributor on any of the following grounds:

(1) The applicant has been found by the Board or by a court to have violated the pharmacy or drug laws or rules of this state or of any other state or of the federal government.

(2) The applicant has been convicted of any offence under federal, state, or local laws.

(3) The applicant has a history of non-compliance with state or federal rules or laws regulating the manufacture, distribution, or dispensing of drugs.

(4) The applicant has made a material misrepresentation to the Board in the course of applying for an initial or renewal of registration.

(5) Disciplinary action has been taken by the federal government or by any state, or local government regarding any license or registration currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs.

(6) The applicant has engaged in any conduct involving moral turpitude.
(7) The Board determines that granting the registration is not consistent with the public health or safety or is otherwise not in the public interest.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.135, 689.155, 689.305, 689.315 & 689.405
Hist.: PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06

855-065-0009
Personnel

As a part of the registration or re-registration application, an applicant for registration as a Class I Wholesaler must name a Designated Representative (DR) for each wholesale distributor registered under these rules. The DR must:

(1) Be employed in a full-time managerial position by the wholesale distributor and may not be listed as the DR for more than one registrant without the specific written authority of the Board.

(2) Have at least two years verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale distributor registered under these rules or with another state.

(3) Have verifiable experience in record keeping and storage of prescription drugs.

(4) Be actively involved in and aware of the daily operations of the wholesale distributor.

(5) Be knowledgeable about all policies and procedures of the wholesale distributor.

(6) Be physically present at the wholesale distributor during normal business hours, which must be posted to be visible to the public, except when absent due to emergency, authorized absence or legitimate business reason (as used in this rule, "normal business hours" means at least six hours between 6.00 am and 7.00 pm on at least five days between Monday and Saturday every week, excluding national and local holidays). Class I wholesalers located within Oregon must designate a replacement DR and notify the Board accordingly, when any absence of the DR exceeds 15 days.

(7) The DR must conduct a self-inspection of the facility by September 1 each year, and document the results of this self-inspection on Oregon Wholesaler Self-Inspection Form provided by the Board. The DR must certify in writing, under penalties of perjury, that the information recorded on the Oregon Wholesaler Self-Inspection Form is correct. This form must be retained for three years and must be made available to the Board within two days upon request.

(8) The DR must ensure that the wholesale drug outlet has policies and procedures in effect and implemented to ensure that the outlet employs adequate personnel with the education and experience necessary to engage in the wholesale distribution of drugs safely and lawfully.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.315, 689.325
Hist.: PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06

855-065-0010
Minimum Requirements for Record Keeping and Inventory Management

(1) A Wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records must comply with all federal drug laws and regulations unless exempted.

(2) Inventories and records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, law enforcement agencies, and this Board.

(3) Inventories and records required under these rules must be maintained for a minimum of three years following disposition of the drugs.

(4) Records described in this section that are less than 13 months old must be kept at the inspection site or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by this rule must be made available for inspection within three business days of a request.

(5) A wholesale distributor must establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of drugs, including policies and procedures for identifying, recording, and reporting any loss, theft, counterfeiting or diversion of any drug and for correcting all errors and inaccuracies in inventories. A wholesale distributor must include in its written policies and procedures the following:

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

(b) A procedure to be followed for handling a recall or withdrawal of a drug. Such procedure must be adequate to deal with a recall or withdrawal due to:

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

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

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

(c) A procedure to prepare for, protect against, and handle any crisis that affects the security or operation of the facility in the event of strike, fire, flood, or other natural disaster, or other local, state, or national emergencies.

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

(e) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(f) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband drugs and reporting of discrepancies within three business days to the Board and any other appropriate state or federal agency.

(g) Reporting of criminal or suspected criminal activities involving the inventory of drugs to the Board within three business days.

(h) Conducting for cause authentication as required under section (7) of this rule.

(i) Procedures for accurately documenting the temperature and humidity conditions of the storage facility.
(6) A wholesale distributor must maintain and adhere to written policies and procedures for all incoming and outgoing product shipments, including but not limited to the following:

(a) Upon receipt, visual examination of each shipping container sufficient to identify the drugs in the container and to determine whether the drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution.

(b) Upon receipt, review of records for accuracy and completeness, considering the:

(A) Total facts and circumstances surrounding each transaction involving the drugs; and

(B) Wholesale distributors involved.

(c) Quarantine of a drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution until:

(A) Examination and a determination is made that the drug is fit for distribution; or

(B) The drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(d) If the wholesale distributor identifies a suspect product, the wholesale distributor must quarantine the product and promptly conduct an investigation to determine whether the suspect product is illegitimate. If it is determined to be an illegitimate product the wholesale distributor must provide notice to the Board, the Food and Drug Administration, and the trading partners involved in the transaction, within 24 hours.

(e) If the immediate or sealed outer or secondary container or labeling of a drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale distributor must:

(A) Quarantine the drug until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired; and

(B) Provide notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the Board, the Food and Drug Administration, and the manufacturer or wholesale distributor from which the drug was acquired, within 24 hours.

(f) A drug that is not adulterated, misbranded, counterfeit, or suspected counterfeit, but has been opened or used, is identified as such and quarantined until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(g) A drug that will be returned to a manufacturer or wholesale distributor is stored, handled and transported under proper conditions before the return, and documentation showing that proper conditions were maintained must be provided to the manufacturer or wholesale distributor to which the drug is returned.

(h) Inspection of each outgoing shipment to verify the identity of each drug and to ensure that each drug has not been damaged in storage or held under improper conditions.

(i) Contraband, counterfeit, or suspected counterfeit drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the Board or the Food and Drug Administration.

(j) Any sealed outer or secondary shipping container or labeling, and accompanying documentation, for a drug that is suspected to be counterfeit or fraudulent, is retained until a disposition is authorized by the Board and the Food and Drug Administration.

(k) Operations comply with all state and federal laws, rules and regulations applicable to wholesale drug distribution.

(l) All confidential information is stored in an area with restricted access and in such a way as to protect the integrity and confidentiality of the information.

(7) A wholesale distributor must maintain pedigree records for a minimum of three years.

(8) If the wholesale distributor is involved in the distribution of controlled substances, the distributor must register with the Drug Enforcement Administration and the Board, and comply with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances including, but not limited to, the isolation of controlled substances from non-controlled substances and storage of the controlled substances in a secure area in accordance with Drug Enforcement Administration security requirements and standards.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.315, 689.325 & 689.765
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 3-1992, f. & cert. ef. 3-26-92 (and corrected 4-8-92); BP 12-2006, f. & cert. ef. 12-19-06; BP 4-2015, f. & cert. ef. 7-1-15

855-065-0012
Storage of Drugs

(1) As a condition for receiving and retaining a wholesale distributor registration issued under these rules, an applicant must satisfy the Board that the applicant has and will continuously maintain acceptable storage and handling conditions and facilities standards for each facility at which drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which drugs are transported, including:

(a) Suitable construction of the facility and appropriate monitoring equipment to ensure that drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards.

(b) Suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.

(c) Adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(d) A quarantine area for the separate storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened.

(e) Maintenance of the facility in a clean and orderly condition.

(f) Maintenance of the facility in a commercial, nonresidential building.

(g) Freedom of the facility from infestation by insects, rodents, birds or vermin of any kind.

(2) The facility must be equipped with appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of drugs.

(3) The facility must meet security standards including but not limited to:

(a) Access controls that restrict access to areas where drugs are held, to authorized personnel.

(b) An after hours central alarm or a comparable entry detection system.

(c) Adequate outside perimeter lighting.

(d) Safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155 & 689.305
Hist.: BP 12-2006, f. & cert. ef. 12-19-06

855-065-0013
Prohibited Practices

(1) The following practices are expressly prohibited:

(a) A wholesale distributor may not purchase drugs from a closed-door pharmacy.

(b) A wholesale distributor may not sell, distribute or transfer a drug to a person who is required by the laws and rules of Oregon to be registered with the Oregon Board of Pharmacy and who is not appropriately registered by the Board. Before furnishing a drug to any person not known to the wholesale distributor, the wholesale distributor must verify that the person is legally authorized to receive the drug.

(c) A wholesale distributor may not purchase any drug from a person who is required by the laws and rules of Oregon to be registered with the Oregon Board of Pharmacy and who is not appropriately registered by the Board. Before purchasing a drug from any person not known to the wholesale distributor, the wholesale distributor must verify that the person is legally authorized to sell the drug.

(d) A Class 1 Wholesaler who is classified as a "Specialty Wholesaler Distributor" as defined in OAR 855-065-005(20) may not:

(A) Sell, distribute or transfer a prescription drug to a pharmacy or to a practitioner who is licensed to prescribe the prescription drug, without providing a complete pedigree for the prescription drug, unless the prescription drug was purchased directly from the manufacturer or from the manufacturer's authorized distributor of record.

(B) Sell, distribute or transfer a prescription drug to a wholesale distributor, without providing a complete pedigree for the prescription drug.

(2) A wholesaler may not perform, cause the performance of, or aid the performance of any of the following:

(a) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.

(b) The adulteration, misbranding, or counterfeiting of a drug.

(c) The intentional receipt of a drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected product, and the delivery or proffered delivery of the drug for pay or otherwise.

(d) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a drug or the commission of another act with respect to a drug that results in the drug being misbranded.

(e) The forging, counterfeiting, simulating, or falsely representing a drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

(f) The purchase or receipt of a drug from a person that is not registered to distribute drugs to the purchaser or recipient.
(g) The sale or transfer of a drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug, to purchase or receive drugs from the person selling or transferring the drug.
(h) The failure to maintain or provide records as required under these rules.

(i) Providing the Board, a representative of the Board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to these rules.

(j) Participating in the wholesale distribution of a drug that was:

(A) Purchased by a public or private hospital or other health care entity under the terms of an "own-use" contract; or

(B) Donated or supplied at a reduced price to a charitable organization; or

(C) Stolen or obtained by fraud or deceit; or

(D) Illegally imported into the USA.

(k) Obtaining or attempting to obtain a drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a drug.

(l) Failing to maintain required pedigree records.

(m) Receiving a prescription drug through wholesale distribution without receiving a required pedigree attested to as accurate and complete by the wholesale distributor.

(n) Distributing a drug that was previously dispensed by a retail pharmacy or a practitioner.

(o) Failing to report an act prohibited by any of the rules in OAR 855.065 to the appropriate state or federal authorities.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305, 689.315 & 689.527
Hist.: BP 12-2006, f. & cert. ef. 12-19-06; BP 4-2015, f. & cert. ef. 7-1-15

BOARD OF PHARMACY

DIVISION 70
PROPHYLACTICS AND CONTRACEPTIVES

855-070-0001
Definitions

(1) Prophylactic means a drug, device or medical preparation intended for or having special utility in the prevention of a sexually transmitted disease, or in the prevention of conception.

(2) Contraceptive means a drug, device or medical preparation intended for the prevention of conception.

(3) Male condom means a prophylactic or contraceptive device in the form of a sheath which completely covers the penis with a closely fitting membrane.

(4) Female condom means a prophylactic or contraceptive device in the form of an intravaginal pouch that consists of a sheath with a flexible ring on each end.

Stat. Auth.: ORS 689.155 & 689.205
Stats. Implemented:
Hist.: PB 1-1995, f. & cert. ef. 4-27-95

855-070-0005
Applications, Fees, and Licenses to Sell Prophylactics and Contraceptives

(1) Every wholesaler or manufacturer of prophylactics or contraceptives who distributes in Oregon goods of the class specified in ORS 435.010 shall annually submit an application for a license issued by the Board of Pharmacy:

(a) The application shall be made in writing on a form prepared by the Board and be accompanied by the fee listed in division 110;

(b) One such application shall be submitted and license obtained for each location or separate address from which goods are distributed;

(c) Licenses shall be issued upon receipt of the fee listed in division 110 and shall be in effect for one year from January 1 of each year. Licenses are not transferable;

(d) Licenses shall be publicly or conspicuously displayed and the wholesaler or manufacturer to whom they are issued shall be open to inspection by the Board or other authorized persons designated by the Board;

(e) Each application for a license shall include a list of all products or brands of prophylactics and contraceptives the applicant wishes to have approved for sale in the state.

(2) Before any condom product can be distributed in Oregon, it must be approved by the Oregon Board of Pharmacy. Every manufacturer or wholesaler that intends to distribute either male or female condoms shall furnish to the Board the names of such products.

(3) The Board may require proof to be furnished by the manufacturer or wholesaler that these products have received approval in accordance with the Federal Food, Drug and Cosmetic Act and regulations thereunder (Title 21 U.S.C. and CFR);

(4) The requirements under the Federal Food, Drug and Cosmetic Act and regulations thereunder (Title 21 U.S.C. and CFR) relating to prophylactics and contraceptives are adopted by reference and made a part hereof.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 435.010, 435.080, 435.100 & 689.155
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 29(Temp), f. & ef. 9-6-73; 1PB 32, f. 1-31-74, ef. 2-25-74; 1PB 35(Temp), f. & ef. 3-26-74; 1PB 36, f. 7-1-74, ef. 7-25-74; 1PB 39, f. & ef. 1-8-76; PB 10-1987, f. & ef. 12-8-87; PB 1-1995, f. & cert. ef. 4-27-95; BP 10-2006, f. & cert. et. 12-19-06

855-070-0010
Labeling and Storage of Prophylactics and Contraceptives

(1) The use of detachable slip labels or removable ink stamps listing names and addresses of manufacturer, brand name, and expiration date do not meet the labeling requirements of ORS 435.090.

(2) As of December 31, 1994, all prophylactics and contraceptives shall bear an expiration date. Prophylactics and contraceptives bearing an expiration date shall not be sold or otherwise distributed beyond that date.

(3) Prophylactics and contraceptives shall be stored, displayed, or sold from an area removed from excessive extremes of temperatures which may affect the quality of the products.
Stat. Auth.: ORS 689.155 & 689.205

Stats. Implemented:
Hist.: 1PB 18, f. & ef. 10-14-64; 1PB 29(Temp), f. & ef. 9-6-73 thru 1-3-74; 1PB 32, f. 1-31-74, ef. 2-25-74; 1PB 39, f. & ef. 1-8-76; 1PB 1-1984, f. & ef. 2-16-84; PB 1-1995, f. & cert. ef. 4-27-95

BOARD OF PHARMACY

DIVISION 80
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0015
Definitions

As used in these rules:

(1) "Act" means the Uniform Controlled Substances Act, ORS Chapter 475, and rules thereunder;

(2) "CFR" means Code of Federal Regulations;

(3) The term "registration" or variants thereof means the annual registration required of manufacturers, distributors and dispensers of controlled substances under ORS 475.125, and the term "registrants" or variants thereof refers to persons so registered; provided that where references of this nature are used in CFR sections referred to in these rules, the reference is to the registration requirements and registrants under the Federal Controlled Substances Act, and Title 21, CFR.

(4) "USC" means United States Code;

(5) Terms not defined in this rule have the definitions set forth in ORS 475.005.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035 & 475.940
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 5-1991, f. & cert. ef. 9-19-91; BP 3-2002(Temp), f. & cert. ef. 3-1-02 thru 8-23-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0020
Schedules

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 U.S.C. Sections 811 to 812 and as amended by the Board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; 1PB 2-1984, f. & ef. 3-7-84; 1PB 4-1984(Temp), f. & ef. 9-17-84; 1PB 1-1985, f. & ef. 2-27-85; 1PB 2-1985, f. & ef. 7-24-85; 1PB 4-1985, f. & ef. 12-2-85; 1PB 2-1986, f. & ef. 7-10-86; PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

(5) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) Marijuana and delta-9-tetrahydrocannabinol (THC).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059 & 475.065
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 8-1987, f. & ef. 9-30-87; PB 10-1987, f. & ef. 12-8-87; PB 15-1989, f. & cert. ef. 12-26-89; PB 9-1990, f. & cert. ef. 12-5-90; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 4-2000, f. & cert. ef. 2-16-00; BP 9-2000, f. & cert. ef. 6-29-00; BP 2-2002(Temp), f. & cert. ef. 2-4-02 thru 7-31-02; BP 3-2002(Temp), f. & cert. ef. 3-1-02 thru 8-23-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 5-2002, f. & cert. ef. 11-14-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10; BP 10-2010(Temp), f. & cert. ef. 10-15-10 thru 4-11-11; BP 2-2011, f. & cert. ef. 4-11-11; BP 9-2013, f. & cert. ef. 10-28-13; BP 11-2013(Temp), f. & cert. ef. 12-20-13 thru 6-18-14; BP 4-2014(Temp), f. 2-27-14, cert. ef. 2-28-14 thru 8-27-14; BP 5-2014(Temp), f. & cert. ef. 4-15-14 thru 8-27-14; BP 7-2014, f. & cert. ef. 6-18-14; BP 3-2016(Temp), f. & cert. ef. 8-22-16 thru 2-17-17; BP 6-2016, f. & cert. ef. 12-14-16

855-080-0022
Schedule II

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.12 and any quantity of the following substances:

(1) Marijuana and delta-9-tetrahydrocannabinol (THC).

(2) Methamphetamine, when in the form of an FDA approved product containing methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059 & 475.065
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 8-1987, f. & ef. 9-30-87; PB 10-1987, f. & ef. 12-8-87; PB 15-1989, f. & cert. ef. 12-26-89; PB 9-1990, f. & cert. ef. 12-5-90; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 3-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 4-2000, f. & cert. ef. 2-16-00; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15

855-080-0023
Schedule III

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.13; and

(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.

(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.

(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 11-1989, f. & cert. ef. 7-20-89; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); BP 3-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 4-2000, f. & cert. ef. 2-16-00; BP 9-2000, f. & cert. ef. 6-29-00; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0024
Schedule IV

Schedule IV consists of:

(1) The drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.14, unless specifically excepted or listed in another schedule: and

(2) Products containing carisoprodol or the salts of carisoprodol as an active ingredient.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1995, f. & cert. ef. 4-27-95; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 4-2000, f. & cert. ef. 2-16-00; BP 9-2000, f. & cert. ef. 6-29-00; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0026
Schedule V

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.15.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 5-1991, f. & cert. ef. 9-19-91; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0028
Excluded Substances

The following drugs and their generic equivalents are excepted from the schedules in OAR 855-080-0021 through 855-080-0026:

(1) Benzedrex inhaler (Propylhexedrine).

(2) Vicks -- Vapor inhaler (Levmetamfetamine).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 4-1987, f. & ef. 3-30-87; Renumbered from 855-080-0025; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1995, f. & cert. ef. 4-27-95; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 6-2006(Temp), f. & cert. ef. 8-25-06 thru 1-31-07; BP 8-2006, f. & cert. ef. 12-19-06; BP 8-2010, f. & cert. ef. 6-29-10

Registration of Manufacturers, Distributors and Dispensers

855-080-0031
Registration Requirements

Manufacturers, distributors, and pharmacies or other drug outlets are required to register with the Board under the Uniform Controlled Substances Act.

Stat. Auth.: ORS 689.155, 689.205
Stats. Implemented: ORS 475.125
Hist.: 1PB 6-1982, f. & ef. 8-6-82; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0050
Separate Registration for Places of Business

A separate registration is required for each principal place of business where controlled substances are manufactured or from which controlled substances are distributed or dispensed.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82

855-080-0055
Separate Registration for Independent Activities

The manufacturing and distributing of controlled substances are deemed activities independent of each other. A separate registration is required for each activity; however, a person registered to manufacture may distribute or dispense any controlled substance which they are registered to manufacture, provided that, unless specifically exempted, they comply with all requirements and duties prescribed by statute and rules for persons registered to distribute or dispense as applicable.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.125, 689.155
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0065
Security

(1) Applicants for registration and registrants must comply with the security requirements of 21 CFR 1301.02, 1301.71 through 1301.76 and 1301.90 through1301.93, which apply to their registration classification. The requirements of 21 CFR 1301.75 and 1301.76 relating to "practitioners" are applicable to applicants and registrants who are drug dispensers.

(2) The security requirements of subsection one of this rule apply to all "controlled substances," as defined in these rules, except ephedrine, pseudoephedrine and phenylpropanolamine.

(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine and phenylpropanolamine.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.135
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 5-1991, f. & cert. ef. 9-19-91; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0070
Records and Inventory

All registered persons shall, as applicable to the registration classification, keep records and maintain inventories in conformance with 21 U.S.C. Section 827; 21CFR 1304.02 through 1304.11; 1304.21 through 1304.26; 1304.31 through 1304.33; except that a written inventory of all controlled substances shall be taken by registrants annually within 365 days of the last written inventory. All such records shall be maintained for a period of three years.

Stat. Auth.: ORS 475.035, 689.205
Stats. Implemented: ORS 475.165
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; 1PB 1-1986, f. & ef. 6-5-86; PB 10-1987, f. & ef. 12-8-87; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1994, f. & cert. ef. 2-2-94; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07

855-080-0075
Order Forms

Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form in conformance with **21 U.S.C. Section 828** and **21 CFR 1305.01** through **1305.29**.

Stat. Auth.: ORS 475 & 689
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; PB 5-1991, f. & cert. ef. 9-19-91; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06

855-080-0080
Special Exceptions

The provisions of 21 CFR 1307.11 through 1307.13 are applicable under the Act.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; PB 5-1991, f. & cert. ef. 9-19-91; BP 1-2007, f. & cert. ef. 6-29-07

Controlled Substances Prescriptions

855-080-0085
Prescription Requirements

(1) Except as provided in sections (2) and (3) of this rule, the provisions of 21 CFR 1306.01 through 1306.27 and 1304.03(d) shall be complied with by the registrants, practitioners and pharmacists as specified therein in the issuance, preparation, labeling dispensing, recordkeeping and filing of prescriptions for controlled substances. An electronic prescription is permitted for any substance listed in OAR 855-080-0022 through 855-080-0026 when so permitted by federal regulations.

(2) The provisions of 21 CFR 1306.11(a) under section (1) of this rule are amended by deleting "which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act."

(3) The provisions of 21 CFR 1306.21 through 1306.27 under section (1) of this rule shall be deemed to apply also to controlled substances listed in Schedule V.

(4) Controlled substances in Schedules III, IV, and V which are prescription drugs determined by the Board pursuant to ORS 475.185(3) are those prescription drugs as determined under the Federal Food, Drug, and Cosmetic Act. Such drugs are "Legend Drugs" and bear the legend "Caution: Federal law prohibits dispensing without a prescription", or an equivalent legend. In addition, any preparation containing any amount of codeine or its salts, opium, or paregoric in Schedules III, IV, or V is a prescription drug as determined by the Board pursuant to ORS 475.185(3).

(5) "Emergency Situations" as referred to in ORS 475.185(2) mean the same as specified in 21 CFR 290.10.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.185, 475.188
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; 1PB 6-1982, f. & ef. 8-6-82; PB 15-1989, f. & cert. ef. 12-26-89; PB 5-1991, f. & cert. ef. 9-19-91; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10

855-080-0095
Verification of Research Registration

Persons conducting research with controlled substances in Sections I through V within this state who are not otherwise exempt from registration pursuant to ORS 475.125(3), may, upon furnishing the Board a copy of a current federal registration certificate issued for such a purpose, pursuant to ORS 475.135, receive written verification of such submission from the Board's Executive Director.

Stat. Auth.: ORS 475
Stats. Implemented:
Hist.: 1PB 6-1978(Temp), f. & ef. 7-1-78; 1PB 8-1978, f. & ef. 10-17-78; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06

855-080-0100
Animal Euthanasia

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or 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 paid as specified in division 110 of this chapter of rules.

(3) The Board will suspend or revoke the registration of any humane society or animal control agency which allows a person to administer sodium pentobarbital who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

Stat. Auth.: ORS 475.095, 475.190, 689.205
Stats. Implemented: ORS 689.151 & 689.155
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; BP 6-2011(Temp), f. 10-20-11, cert. ef. 10-31-11 thru 4-27-12; BP 7-2011(Temp), f. & cert. ef. 12-15-11 thru 4-27-12; Administrative correction, 5-25-12; BP 3-2012, f. & cert. ef. 6-19-12

855-080-0105
Disposal of Drugs

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

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

(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the following:

(a) The consultant pharmacist or registered nurse designee.

(b) The Director of Nursing Services or supervising nurse designee

(c) The administrator of the facility or an administrative designee

(d) A Registered Nurse employed by the facility

(4) The destruction shall be documented and signed by the witnesses and the document retained at the facility for a period of at least three years. Copies of the document shall be sent to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.

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

Stat. Auth.: ORS 475.035 & 689.205
Stats. Implemented: ORS 689.305
Hist.: 1PB 2-1984, f. & ef. 3-7-84; PB 1-1989, f. & cert. ef. 1-3-89; PB 1-1990, f. & cert. ef. 1-23-90; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1996, f. & cert. ef. 4-5-96; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 8-2010, f. & cert. ef. 6-29-10

BOARD OF PHARMACY

DIVISION 110 FEES

855-110-0003
General

(1) All fees paid under these rules are non-refundable.

(2) Fees cannot be prorated.

(3) Fees for initial licensure as a Pharmacist or Certified Oregon Pharmacy Technician may be reduced to one half of a biennial rate, if the application is received or the mailing date of the application is postmarked within 180 days of expiration.

(4) A delinquent fee must be paid:

(a) When an application is postmarked after the date specified in these rules; or

(b) When the Board requests additional information from an applicant and this information is not provided within 30 days.

(5) A delinquent fee may be assessed when an application is submitted incomplete and the Board requests the missing information.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.135
Hist.: BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 13-2014, f. 12-30-14, cert. ef. 4-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-110-0005
Licensing Fees

(1) Pharmacist license examination (NAPLEX) and re-examination fee — $50.

(2) Pharmacist jurisprudence (MPJE) re-examination fee — $25.

(3) Pharmacist licensing by reciprocity fee — $200*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(4) Pharmacist licensing by score transfer fee — $200*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(5) Intern license fee. Expires November 30 every two years — $50.

(6) Pharmacist:

(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is — $120. Delinquent renewal fee, (postmarked after May 31) — $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially— $50. (This is a mandatory fee, required by ORS 431.972 that must be paid with the pharmacist license renewal fee).
(c) Workforce Data Collection fee. Due by June 30 biennially — $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.

(7) Certification of approved provider of continuing education course fee, none at this time.

(8) Pharmacy Technician license fee — $50.

(a) A Pharmacy Technician license initially issued prior to January 1, 2015 to a person under 18 years of age expires June 30 in odd numbered years — $50. Delinquent renewal fee, (postmarked after May 31) — $20.

(9) Certified Oregon Pharmacy Technician:

(a) Biennial license fee. Expires June 30 each even numbered year — $50. Delinquent renewal fee, (postmarked after August 31) — $20.

(b) Workforce Data Collection fee. Due by June 30 biennially — $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.

Stat. Auth.: ORS 689.205 & 291.055 & 183.705
Stats. Implemented: ORS 689.135, 431.972 & 676.410
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 3-1980, f. 5-3-80, ef. 5-3-80 & 7-1-80; 1PB 2-1982, f. 3-8-82, ef. 4-1-82; 1PB 1-1984, f. & ef. 2-16-84; 1PB 3-1985, f. & ef. 12-2-85; PB 3-1988, f. & cert. ef. 5-23-88; PB 7-1989, f. & cert. ef. 5-1-89; PB 15-1989, f. & cert. ef. 12-26-89; PB 10-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 4-1992, f. & cert. ef. 8-25-92; PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 2-1997(Temp), f. 10-2-97, cert. ef. 10-4-97; BP 2-1998, f. & cert. ef. 3-23-98; BP 1-2001, f. & cert. ef. 3-5-01; BP 2-2001(Temp), f. & cert. ef. 7-26-01 thru 1-22-02; BP 1-2002, f. & cert. ef. 1-8-02; BP 1-2003, f. & cert. ef. 1-14-03; BP 1-2006, f. & cert. ef. 6-9-06; BP 5-2006(Temp), f. & cert. ef. 8-25-06 thru 1-20-07; BP 9-2006, f. & cert. ef. 12-19-06; BP 5-2009, f. & cert. ef. 12-24-09; BP 5-2010(Temp), f. 5-3-10, cert. ef. 5-4-10 thru 10-30-10; BP 6-2010, f. & cert. ef. 6-29-10; BP 5-2011(Temp), f. 6-24-11, cert. ef. 7-1-11 thru 12-27-11; BP 8-2011, f. & cert. ef. 12-15-11; BP 2-2013(Temp), f. 4-4-13, cert. ef. 4-5-13 thru 9-28-13; BP 3-2013(Temp), f. 6-27-13, cert. ef. 7-1-13 thru 12-28-13; BP 4-2013(Temp), f. & cert. ef. 7-9-13 thru 1-5-14; BP 7-2013, f. & cert. ef. 9-23-13; BP 1-2014, f. & cert. ef. 1-3-14; BP 13-2014, f. 12-30-14, cert. ef. 4-1-15; BP 4-2015, f. & cert. ef. 7-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-110-0007
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) Community Health Clinic. Expires March 31 annually — $75*. Delinquent renewal fee (postmarked after February 28) — $25. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(2) Drug Distribution Agent. Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.

(3) Drug Room (including correctional facility). Expires March 31 annually — $75*. Delinquent renewal fee (postmarked after February 28) — $75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.
(5) Medical Device, Equipment & Gas Class C. Expires January 31 annually — $50. Delinquent renewal fee (postmarked after December 31) — $25.

(6) Nonprescription Class A. Expires January 31 annually — $50. Delinquent renewal fee (postmarked after December 31) — $25.

(7) Nonprescription Class B. Expires January 31 annually — $50. Delinquent renewal fee (postmarked after December 31) — $25.

(8) Nonprescription Class D. Expires January 31 annually — $100. Delinquent renewal fee (postmarked after December 31) — $25.

(9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer — $50*. Expires December 31 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(10) Re-inspection fee — $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(11) Retail or Institutional Drug Outlet. Expires March 31 annually — $175*. Delinquent renewal fee (postmarked after February 28) — $75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.

(13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually — $100. Due by February 28 annually.

(14) Charitable Pharmacy. Expires March 31 annually — $75. Delinquent renewal fee (postmarked after February 28) — $25.

(15) Home Dialysis. Expires March 31 annually — $175*. Delinquent renewal fee (postmarked after February 28) — $75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(16) Supervising Physician Dispensing Outlet. Expires March 31 annually — $175*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Delinquent renewal fee (postmarked after February 28) — $75.

Stat. Auth.: ORS 689.205 & 291.055
Stats. Implemented: ORS 689.135, 689.774 & 2689.305
Hist.: PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 3-1998, f. & cert. ef. 3-23-98; BP 2-2001(Temp), f. & cert. ef. 7-26-01 thru 1-22-02; BP 1-2002, f. & cert. ef. 1-8-02; BP 4-2002, f. 6-27-02, cert. ef. 7-1-02; BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 6-2010, f. & cert. ef. 6-29-10; BP 5-2011(Temp), f. 6-24-11, cert. ef. 7-1-11 thru 12-27-11; BP 8-2011, f. & cert. ef. 12-15-11; BP 5-2012(Temp), f. & cert. ef. 6-19-12 thru 12-16-12; BP 6-2012, f. & cert. ef. 12-13-12; BP 3-2013(Temp), f. 6-27-13, cert. ef. 7-1-13 thru 12-28-13; BP 4-2013(Temp), f. & cert. ef. 7-9-13 thru 1-5-14; BP 7-2013, f. & cert. ef. 9-23-13; BP 1-2014, f. & cert. ef. 1-3-14; BP 4-2015, f. & cert. ef. 7-1-15; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-110-0010
Fees for Registration for Controlled Substances under ORS 475.095

(1) Animal Euthanasia controlled substance registration fee — $50 annually.
(2) Drug Distribution Agent controlled substance registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(3) Drug Room (including correctional facility) controlled substance registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(4) Manufacturer controlled substance registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(5) Retail or Institutional Drug Outlet controlled substance registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(6) Schedule II Precursor registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(7) Wholesaler controlled substance registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

(8) Remote Distribution Facility controlled substance registration fee — $50* annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

Stat. Auth.: ORS 689.205 & 291.055
Stats. Implemented: ORS 689.135
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; 1PB 6-1982, f. & ef. 8-6-82; 1PB 2-1984, f. & ef. 3-7-84; PB 15-1989, f. & cert. ef. 12-26-89; PB 10-1990, f. & cert. ef. 12-5-90; PB 3-1991, f. & cert. ef. 9-19-91; PB 1-1996, f. & cert. ef. 4-5-96; BP 2-2005, f. 2-14-05, cert. ef. 3-1-05; BP 2-2009(Temp), f. 6-22-09, cert. ef. 6-26-09 thru 12-23-09; BP 5-2009, f. & cert. ef. 12-24-09; BP 5-2011(Temp), f. 6-24-11, cert. ef. 7-1-11 thru 12-27-11; BP 8-2011, f. & cert. ef. 12-15-11; BP 3-2013(Temp), f. 6-27-13, cert. ef. 7-1-13 thru 12-28-13; BP 4-2013(Temp), f. & cert. ef. 7-9-13 thru 1-5-14; BP 7-2013, f. & cert. ef. 9-23-13; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

855-110-0015
Administrative Fees

(1) The Board of Pharmacy may charge a fee reasonably calculated to reimburse the agency for costs of providing and conveying copies of public records, and other administrative services.

(2) All fees and charges must be paid before public records will be available for inspection or copies provided.

(3) Costs include but are not limited to:

(a) The services and supplies used in making the records available;

(b) The time spent locating the requested records, reviewing the records, and redacting or separating material exempt from disclosure;

(c) Supervising a person's inspection of original documents;

(d) Copying records;

(e) Certified copies of records and licenses;

(f) Summarizing, compiling or organizing the public records to meet the person’s request;

(g) Searching for and reviewing records even if the records subsequently are determined to be exempt from disclosure;

(h) Postal and freight charges for shipping the copies of the public records sent first class or bulk rate based on weight;

(i) Indirect costs or third party charges associated with copying and preparing the public records;

(j) Costs associated with electronic retrieval of records;

(k) Actual costs charged by the Attorney General's office for attorney's time spent in reviewing and redacting material from the records, and in separating material into exempt and nonexempt records. A fee may not be charged for the cost of time spent by an attorney in determining the application of the provisions of ORS 192.410 to 192.505;

(L) Staff time for performing the work;

(m) The cost of publications will be based on the actual costs of development, printing and distribution as determined by the Board;

(4) The Board shall establish and publish a list of fees used to charge requestors for the costs of preparing and making available the following and shall review the schedule at least once a biennium and any time an increase is proposed, to assure that the fees reflect current Board costs:

(a) Photocopies;

(b) Facsimile copies. The Board may limit the transmission to twenty pages;

(c) Electronic copies, CDs, DVDs, and other electronically generated materials including lists electronically mailed from the Board database. The Board shall determine what electronic media for reproduction of computer records may be used and whether the electronic media is to be provided by the Board or the requestor;

(d) Manual license verification;

(e) Publications including but not limited to:

(A) Copies of Laws and Rules;

(B) The newsletter.

(f) Licensee duplicate wall certificates;

(g) Duplicate renewal forms;

(h) Re-mailing of returned mail when a licensee or registrant has failed to notify the Board of a change of address.

(5) No additional fee may be charged for providing records or documents in an alternative format when required by the Americans with Disabilities Act.

(6) The Board shall notify requestors of the estimated fees for making the public records available for inspection or for providing copies to the requestor. If the estimated fees exceed $25, the Board shall provide written notice and may not act further to respond to the request until the requestor notifies the Board, in writing, to proceed with making the records available.

(7) The Board or its designee may reduce or waive any of the above administrative fees when a determination is made that the waiver or reduction of fees is in the public interest. Factors that may be taken into account in making such a determination include, but are not limited to:

(a) The overall costs incurred by the Board are negligible; or

(b) Providing the requested records or documents is within the normal scope of the Board's activity; or

(c) Requiring payment would cause extreme or undue financial hardship upon the requestor; or

(d) The request is a discovery request made as part of pending administrative, judicial or arbitration proceedings.

(8) If the Board denies an application for waiver or reduction of fees, the requestor may petition the Attorney General under the provisions of ORS 192.440(5) and 192.450.

(9) The Board establishes the following fees for inspection of out-of-state registrants. When an applicant for registration or renewal of registration requests an inspection, the Board shall execute an agreement with the applicant that must specify that the applicant shall pay:

(a) The travel expenses of each Board staff person (inspector) by coach-class commercial air or by rental car;

(b) The hotel costs of the inspector, subject to the applicant arranging accommodation in a hotel that is, whenever possible, on the federal per-diem list;

(c) Rental car costs for the inspector unless the applicant provides adequate ground transportation;

(d) The per-diem expenses of the inspector;

(e) A fee for the Board's time and expenses calculated as:

(A) The daily compensation of the inspector, plus the costs of any fringe benefits charged to the Board, multiplied by: one plus the number of days or partial days the inspector is away from their normal workplace; plus

(B) An administrative fee of $750.

(10) In addition to the reinspection fee specified in OAR 855-110-0007, the Board establishes the following administrative fees for a re-inspection of any Oregon drug outlet that is necessary to verify corrections of violations found on an initial inspection:

(a) The travel, hotel and per-diem costs for the inspector; and

(b) The hourly compensation of the inspector plus the cost of any fringe benefits charged to the Board multiplied by the number of hours necessary for the reinspection.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 192.430 & 192.440
Hist.: PB 10-1990, f. & cert. ef. 12-5-90; PB 1-1996, f. & cert. ef. 4-5-96; BP 2-2010, f. 2-12-10, cert. ef. 3-1-10