Chapter 246-945 WAC
PHARMACY QUALITY ASSURANCE COMMISSION

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WAC

PART 1 - GENERAL PROVISIONS

246-945-001 Definitions.

Subpart A - Commission Operations

246-945-002 Administrative proceedings and appeals.
246-945-005 Commission inspections and investigations.

Subpart B - Prescription Labeling, Records, and Advertising

246-945-010 Prescription and chart order—Minimum requirements.
246-945-011 Prescription validity.
246-945-012 Prescription refills.
246-945-013 Partial filling of prescriptions.
246-945-014 Electronic prescribing mandate waiver.
246-945-015 Minimum requirements for dispensing practitioners.
246-945-016 Prescriptions—Outpatient labels—Minimum requirements.
246-945-017 Prescriptions—Hospital inpatient labels—Minimum requirements.
246-945-018 Prescriptions—Labeling—Prepackage medications.
246-945-020 Records retention period and commission access to records.
246-945-025 Prescription drug price advertising.

Subpart C - Legend Drugs and Controlled Substances

246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW.
246-945-031 Ephedrine prescription restrictions.
246-945-032 Child-resistant containers.
246-945-033 Over-the-counter drugs.
246-945-035 Drug sample prohibitions.
246-945-037 Regulated steroids.
246-945-038 Availability and identity of amygdalin.
246-945-040 Uniform Controlled Substance Act.
246-945-043 Designation of nonnarcotic stimulant drugs for the purposes of RCW 69.50.402 (1)(c).
246-945-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants.
246-945-047 Sodium pentobarbital registration disciplinary action.
246-945-050 Commission authority to control.
246-945-051 Schedule I.
246-945-052 Schedule II.
246-945-053 Schedule II immediate precursors.
246-945-054 Schedule III.
246-945-055 Schedule IV.
246-945-056 Schedule V.
246-945-060 Other controlled substance registrants—Requirements.
246-945-063 Precursor definitions.
246-945-065 Precursor substance control.
246-945-070 Reports of precursor receipt.
246-945-072 Precursor substance monthly reporting.
246-945-075 Suspicious transactions and reporting requirements.
246-945-077 Precursor substance requirements for the sale of a restricted product.
246-945-078 Record of sales—Electronic methamphetamine precursor tracking.
246-945-080 Acceptable forms of identification.
246-945-085 Maintenance of and access to retail sales records of restricted products.
246-945-087 Exemptions from electronic reporting.
246-945-088 Denial of a sale—Override.

Subpart D - Home Dialysis

246-945-090 Home dialysis program—Legend drugs.
246-945-091 Home dialysis program—Pharmacist consultant.
246-945-092 Home dialysis program—Records.
246-945-093 Home dialysis program—Quality assurance.

Subpart E - Compounding

246-945-100 Compounding minimum standards.

PART 2 - GENERAL LICENSING

246-945-145 License required.
246-945-150 Applicable forms.

Subpart A - Pharmacy Interns and Pharmacist

246-945-155 Pharmacy interns—Registration requirements.
246-945-156 Pharmacy intern—Temporary practice permit.
246-945-162 Pharmacist license qualifications.
246-945-163 Certification of internship hours.
246-945-165 Pharmacist licensure and jurisprudence examinations.
246-945-170 Pharmacist licensure by license transfer—Temporary practice permits.
246-945-171 Retired active pharmacist license status.
246-945-173 Expired pharmacist license.
246-945-175 Inactive pharmacist license.

246-945-178 Pharmacist continuing education.
246-945-180 Nuclear pharmacist endorsement.

Subpart B - Pharmacy Assistants and Technicians

246-945-200 Pharmacy assistants.
246-945-203 Pharmacy technician-in-training authority for experiential training.
246-945-205 Pharmacy technician certification.
246-945-210 Pharmacy technician—Temporary practice permit—Military spouse eligibility and issuance.
246-945-215 Pharmacy technician education and training programs.
246-945-217 Expired pharmacy technician certification.
246-945-220 Pharmacy technician—Continuing education.

Subpart C - Pharmaceutical Firm Licensing

246-945-230 General information, change of location, ownership or new construction.
246-945-232 Pharmacy licensing.
246-945-233 Hospital pharmacy associated clinics.
246-945-235 Nonresident pharmacy license.
246-945-245 Health care entity license.
246-945-246 Wholesaler.
246-945-247 Pharmaceutical manufacturer license.

Subpart D - Commission Registrations

246-945-250 Researcher and other controlled substance registration.
246-945-253 Shopkeeper registration.
246-945-254 Animal control and humane society registration.
246-945-255 Chemical capture—Department of fish and wildlife.

PART 3 - PROFESSIONAL STANDARDS

246-945-305 Pharmacist's professional responsibilities.
246-945-310 Responsible pharmacy manager.
246-945-315 Delegation of pharmacy functions to pharmacy ancillary personnel.
246-945-317 Tech check tech.
246-945-320 Nondelegable tasks.
246-945-325 Patient counseling.
246-945-330 Refilling prescriptions.
246-945-332 Continuity of care.
246-945-335 Prescription adaptation.
246-945-340 Prescriptions—Drug product substitutions.
246-945-345 Prescription transfers.
246-945-350 Collaborative drug therapy agreements.
246-945-355 Monitoring of drug therapy by pharmacist.
246-945-360 Patient rights.
246-945-365 Approval of impaired practitioner substance abuse monitoring program.
246-945-370 Sexual misconduct.

PART 4 - OPERATIONAL STANDARDS

Subpart A - Pharmacies, HCEs and HPACs

246-945-405 Applicability.
246-945-410 Facility standards.
246-945-415 Dispensing and delivery of prescription drugs.
246-945-417 Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records.
246-945-418 Paper recordkeeping procedure.
246-945-420 Facility inventory requirements.
246-945-425 Shared pharmacy services.
246-945-430 Pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site.
246-945-435 Provision of emergency department discharge medication when pharmacy services are unavailable.
246-945-440 Administration of patient owned medications.
246-945-445 Investigational drugs.
246-945-450 Accessing technology used to dispense—Nursing students.
246-945-455 Drugs stored outside of the pharmacy.
246-945-460 Staffing and supervision of pharmacy staff.
246-945-480 Facility reporting requirements.
246-945-485 Destruction or return of drugs or devices—Restrictions.
246-945-486 Return and reuse of unexpired medications—Department of corrections.
246-945-488 Safe donation of unexpired prescription drugs.
246-945-490 Nuclear pharmacies.
246-945-492 Nuclear pharmacies—Equipment requirements.

Subpart B - Registrations

246-945-500 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Designated person.
246-945-503 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Authorized personnel.
246-945-505 Humane societies and animal control agencies—Approved legend drugs and approved controlled substances.
246-945-507 Department of fish and wildlife chemical capture programs—Approved legend drugs and approved controlled substances.

246-945-510 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Recordkeeping and reports.
246-945-515 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Drug storage and field use.

Subpart C - Drug Distributors

246-945-550 Manufacturers—Minimum standards.
246-945-553 Teat dip containers.
246-945-555 Wholesaler—Minimum standards—Scope.
246-945-560 Wholesaler—Facility standards.
246-945-565 Wholesaler—Drug storage.
246-945-570 Wholesaler—Drug shipment inspection.
246-945-575 Wholesaler—Recordkeeping.
246-945-580 Wholesaler—Personnel.
246-945-585 Wholesaler—Suspicious orders and due diligence.
246-945-590 Wholesaler—Policies and procedures.
246-945-595 Wholesaler and manufacturer—Prohibited acts.
246-945-600 Salvaging and reprocessing.
246-945-990 Pharmaceutical licensing fees and renewal cycle.
246-945-991 Hospital pharmacy associated clinics fees and renewal cycle.
246-945-992 Fee payment.

PART 1 - GENERAL PROVISIONS

WAC 246-945-001 Definitions. The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

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

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(14) "Commission" means the pharmacy quality assurance commission.

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(21) "Department" means the Washington state department of health.

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

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

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" an electronic device used to send, receive, and/or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" - United States Food and Drug Administration.

(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW 18.64.046 to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(37) "FPGEC" means foreign pharmacy graduate examination committee.

(38) "FPGEE" means foreign pharmacy graduate equivalency examination.

(39) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(40) "HIPAA" means Health Insurance Portability and Accountability Act.

(41) "Hospital" means any institution licensed under chapter 70.41 or 71.12 RCW or designated under RCW 72.23.020.

(42) "Hospital pharmacy" means that portion of a hospital licensed under RCW 18.64.043 which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(43) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system, where the physical address of the office or clinic is identified on a hospital pharmacy license.

(44) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and technician(s).

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(45) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(46) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(47) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(48) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(49) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(50) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTP™).

(51) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(52) "Manual signature" means a printed or wet signature.

(53) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(54) "NABP" means the National Association of Boards of Pharmacy.

(55) "NDC" means National Drug Code.

(56) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(57) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(58) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(59) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(60) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(61) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(62) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(63) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

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

(65) "Precursor drugs" as defined in chapter 69.43 RCW.

(66) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(67) "Protocol" means a written set of procedures, steps or guidance.

(68) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(69) "Radiopharmaceutical" means 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 nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(70) "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.

(71) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(72) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(73) "Secretary" means the secretary of the Washington state department of health.

(74) "Strength" means:

(a) The concentration of the drug product; and/or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(75) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(76) "USP" means the United States Pharmacopeia.

(77) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(78) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(79) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(80) "Virtual wholesaler" means an individual or facility that sells a prescription drug and/or device, but never physically possesses the product.

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

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

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

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

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-001, filed 6/1/20, effective 7/1/20.]

Subpart A - Commission Operations

WAC 246-945-002 Administrative proceedings and appeals. (1) The commission adopts the model procedural rules for boards as adopted by the department, and contained in chapter 246-11 WAC, including subsequent amendments.

(2) The commission adopts the administrative procedures and requirements for credentialed heath care providers as adopted by the department and contained in chapter 246-12 WAC, including subsequent amendments under chapter 246-12 WAC.

(3) Where there is a conflict between the rules incorporated in subsections (1) and (2) of this section, the commission's rule shall supersede.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310,

18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-002, filed 6/1/20, effective 7/1/20.]

WAC 246-945-005 Commission inspections and investigations. (1) Records subject to commission inspection. A pharmaceutical firm shall make available for inspection upon request by the commission or designee records created, maintained, or retained in compliance with statutes or rules enforced by the commission. It is unlawful to refuse to permit or to obstruct a commission inspection.

(2) Initial inspections. Prior to starting a business, as applicable, and upon presentation of appropriate identification, a pharmaceutical firm shall permit the commission, or its designee, to enter and inspect the premises and to audit the records of each entity for compliance with laws enforced by or under the commission's jurisdiction.

(3) Periodic commission inspection. A pharmaceutical firm is subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.

(a) Statement of deficiency.

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

(ii) The commission, or its designee, shall provide a written statement of deficiency to the pharmaceutical firm within ten business days of the exit meeting.

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

(b) Plan of correction. A pharmaceutical firm shall submit a plan of correction to the commission, or its designee, addressing each identified unresolved deficiency within ten business days of receipt of a statement of deficiency.

(i) The commission, or its designee, shall notify the pharmacy within ten business days, whether or not a submitted plan of correction adequately addresses the unresolved deficiencies identified in the statement of deficiency.

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

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

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

(a) The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and

maintain completed worksheets for two years from the date of completion.

(b) When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion.

(5) Inspection informal dispute process.

(a) A pharmaceutical firm may dispute within ten business days:

(i) Any or all deficiencies included on a statement of deficiency issued by the commission;

(ii) The rejection of the first submitted plan of correction;

(iii) The pharmaceutical firm may request a one-time extension.

(b) A pharmaceutical firm shall submit a dispute under this subsection to the commission in writing. The dispute must be in detail and include any supporting documentation for commission consideration.

(c) The commission may review and consider a second rejection of a plan of correction.

(d) The commission shall consider any dispute and notify the pharmaceutical firm of its determination.

(6) Investigations. A pharmaceutical firm shall cooperate with commission investigations conducted to confirm compliance with laws enforced by the commission, to gather information pertinent to a complaint received by the commission, or to enforce disciplinary actions.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-005, filed 6/1/20, effective 7/1/20.]

Subpart B - Prescription Labeling, Records, and Advertising

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R., Chapter II.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R., Chapter II.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-010, filed 6/1/20, effective 7/1/20.]

WAC 246-945-011 Prescription validity. (1) Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity.

(2) A prescription shall be considered invalid if:

(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;

(b) The prescription does not contain the required information as provided in WAC 246-945-010;

(c) The prescription is expired; or

(d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308.

(3) A prescription is considered expired when:

(a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue.

(b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-011, filed 6/1/20, effective 7/1/20.]

WAC 246-945-012 Prescription refills. (1) A prescription for a controlled substance listed in Schedule II cannot be refilled.

(2) A prescription for a controlled substance listed in Schedule III, IV, or V may be refilled a maximum of five times as indicated by the prescriber. The prescription will expire six months after the date of issue pursuant to WAC 246-945-011 even if there are refills remaining.

(3) A prescription for a noncontrolled legend drug may be refilled as indicated by the prescriber in accordance with RCW 18.64.520. There is no limit on the number of refills, but the prescription will expire after twelve months from the date of issue pursuant to WAC 246-945-011.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-012, filed 6/1/20, effective 7/1/20.]

WAC 246-945-013 Partial filling of prescriptions. (1) A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that:

(a) The partial fill is requested by the patient or the prescriber;

(b) The partial filling is recorded in the same manner as a refilling;

(c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and

(d) Partial fills for controlled substances listed in Schedule III through V comply with 21 C.F.R. Sec. 1306.23.

(2) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 C.F.R. Sec. 1306.13, as applicable.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253,

18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-013, filed 6/1/20, effective 7/1/20.]

WAC 246-945-014 Electronic prescribing mandate waiver. (1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312 (2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312 (2)(k).

(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.

(a) For economic hardship and technical limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.

(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.

(3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to:

(a) Economic hardship in the following circumstances:

(i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;

(ii) Opening a new practice after January 1, 2020;

(iii) Intent to discontinue operating in Washington prior to December 31, 2022; or

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of thirty percent medicaid patients.

(b) Technological limitations outside the control of the practitioner if the practitioner is in the process of transitioning to an electronic prescription system.

(c) Other exceptional circumstances include:

(i) The practitioner is providing services at a free clinic;

(ii) The practitioner generates fewer than one hundred prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;

(iii) The practitioner is located in an area without sufficient internet access to comply with the e-prescribing mandate; or

(iv) Unforeseen circumstances that stress the practitioner or health care system in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseeable barriers to electronic prescribing, or unforeseen events that result in a statewide emergency.

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Knowingly submitting a false attestation is grounds for disciplinary action against

a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).

[Statutory Authority: RCW 69.50.312 and 2019 c 314. WSR 21-17-062, § 246-945-014, filed 8/11/21, effective 9/11/21.]

WAC 246-945-015 Minimum requirements for dispensing practitioners. (1) A practitioner authorized to prescribe or administer a legend drug including a controlled substance, other than a pharmacy, can dispense a legend drug including a controlled substance directly to an ultimate user without a prescription.

(2) All practitioners authorized to prescribe legend drugs and who dispense legend drugs directly to the ultimate user shall affix a label to the prescription container that meets the requirements of RCW 69.41.050.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-015, filed 6/1/20, effective 7/1/20.]

WAC 246-945-016 Prescriptions—Outpatient labels—Minimum requirements. (1) All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include:

(a) Drug quantity;

(b) The number of refills remaining, if any;

(c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used;

(d) The name and species of the patient, if a veterinary prescription; and

(e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.

(2) In addition to the requirements in subsection (1) of this section, a compounded product must meet the applicable labeling requirements of USP chapters <795>, <797>, <800>, and <825>. For compounded products, the BUD shall be equivalent to the expiration date required by RCW 18.64.246.

(3) For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account:

(a) The nature of the drug;

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

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

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

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

(f) Any other relevant factors.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-016, filed 6/1/20, effective 7/1/20.]

WAC 246-945-017 Prescriptions—Hospital inpatient labels—Minimum requirements. (1) All licensees of the commission who dispense legend drugs to hospital inpatients shall ensure all drug containers are labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength, when applicable.

(2) In addition to the requirements in subsection (1) of this section, a compounded product dispensed to a hospital inpatient must meet the applicable labeling requirements of USP chapters <795>, <797>, <800>, and <825>.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-017, filed 6/1/20, effective 7/1/20.]

WAC 246-945-018 Prescriptions—Labeling—Prepackage medications. Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, medications dispensed by a pharmacy to a long-term care facility must include a label with the following information:

(1) Drug name;

(2) Drug strength;

(3) Expiration date in accordance with WAC 246-945-016(3);

(4) The manufacturer's name and lot number, if not maintained in a separate record; and

(5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-018, filed 6/1/20, effective 7/1/20.]

WAC 246-945-020 Records retention period and commission access to records. (1) Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later.

(2) A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-020, filed 6/1/20, effective 7/1/20.]

WAC 246-945-025 Prescription drug price advertising. (1) A pharmacy may advertise legend or prescription drug prices provided:

(a) The advertising complies with all state and federal laws, including regulations of the FDA and the Washington State Consumer Protection Act, chapter 19.86 RCW.

(b) The advertising is solely directed towards providing consumers with drug price information and does not promote the use of a prescription drug or drugs to the public.

(c) The drug price advertising shall contain all the following information for all drug products or brand names used in the advertisement:

(i) The proprietary name of the drug product advertised, if any;

(ii) The generic name of the drug product advertised, if any;

(iii) The strength of the drug product advertised. If the drug product advertised contains more than one active ingredient and a relevant strength can be associated with it without indicating each active ingredient, the generic name and quantity of each active ingredient is not required; and

(iv) The price charged for a specified quantity of the drug product.

(2) Advertising of any generic drug that in any way compares a generic drug to a brand name drug may not in any manner imply that the brand name drug is the product offered for sale.

(3) A person, partnership, corporation, association, or agency may not advertise controlled substances for sale to the general public in any manner that promotes or tends to promote the use or abuse of those drugs. Controlled substances may not be physically displayed to the public.

(4) Upon request from the patient, no pharmacy shall refuse to disclose the cost to the specific patient of a prescription drug without third-party reimbursement or discounts.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-025, filed 6/1/20, effective 7/1/20.]

Subpart C - Legend Drugs and Controlled Substances

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications:

(a) The 39th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The 2019 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The 2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"* (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

(3) Copies of the reference material listed in subsection (2) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

(4) The commission also identifies those ephedrine products specified in WAC 246-945-031 as legend drugs under state law.

(5) There may be changes in the marketing status of drugs after the publication of the above references. Upon application of a manufacturer or distributor, the commission may grant authority for the over-the-counter distribution of certain drugs designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-030, filed 6/1/20, effective 7/1/20.]

WAC 246-945-031 Ephedrine prescription restrictions. (1) The commission, under RCW 69.41.075, identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts in the amount of 25 mg. or less per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts are exempt from subsection (1) of this section:

	TRADE NAME	EPHEDRINE CONTENT
1.	AMESAC capsule (Russ)	25 mg. ephedrine HCL
2.	AZMA AID tablet (Various, e.g., Purepac)	24 mg. ephedrine HCL
3.	BRONC-EASE PLUS (Natur-Pharma)	25 mg. ephedrine HCL
4.	BRONCHODILATOR AND EXPECTORANT (PDK Labs)	25 mg. ephedrine HCL

	TRADE NAME	EPHEDRINE CONTENT
5.	BRONITIN tablet (Whitehall)	24 mg. ephedrine HCL
6.	BRONKAID tablet (Breon)	24 mg. ephedrine sulfate
7.	BRONKOLIXER (Sterling Winthrop)	12 mg. ephedrine
8.	BRONKOTABS tablet (Breon)	24 mg. ephedrine sulfate
9.	EFEDRON nasal jelly (Hyrex)	0.6% ephedrine HCL in 20 g.
10.	MINI THINS asthma relief (BDI Pharmaceuticals)	25 mg. ephedrine
11.	PAZO HEMORRHOID suppository (Bristol-Meyers)	3.86 mg. ephedrine sulfate
12.	PAZO HEMORRHOID ointment (Bristol-Meyers)	0.2% ephedrine sulfate
13.	PRIMATENE tablet (Whitehall)	24 mg. ephedrine HCL
14.	PRIMATENE M tablet (Whitehall)	24 mg. ephedrine HCL
15.	PRIMATENE P tablet (Whitehall)	24 mg. ephedrine HCL
16.	QUELIDRINE (Abbott)	5 mg. ephedrine HCL
17.	TEDRAL tablet (Parke-Davis)	24 mg. ephedrine HCL
18.	THEODRINE tablet (Rugby)	25 mg. ephedrine HCL
19.	VATRONOL nose drops (Vicks Health Care)	0.5% ephedrine sulfate

(3) Ma Huang or other botanical products of genus ephedra used in their natural state and containing 25 mg. or less of ephedrine per recommended dosage as a preparation for human consumption are not legend drugs for the purposes of this section.

(4) Any reformulation of listed products which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms shall negate the exemption. The manufacturers of listed products shall notify the commission of any reformulation which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms prior to distributing that product in the state of Washington.

(5) Manufacturers of products containing 25 mg. or less of ephedrine per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts may gain exemption from subsection (1) of this section if, prior to the distributing of any such product in the state of Washington, the manufacturer:

(a) Provides the commission with the formulation of any such product;

(b) Provides the commission samples of all dosage forms in which the product is to be marketed in the packaging in which the product is to be marketed; and

(c) Receives the commission's approval to market such product.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-031, filed 6/1/20, effective 7/1/20.]

WAC 246-945-032 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 C.F.R., Part 1700, unless:

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

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

(2) No pharmacist or pharmacy employee may designate themselves as the patient's agent.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-032, filed 6/1/20, effective 7/1/20.]

WAC 246-945-033 Over-the-counter drugs. Except as provided in 21 C.F.R. 206.1 et seq., no nonimprinted solid dosage form drug that is intended for OTC sale may be distributed into or sold in the state of Washington unless it has been found by the commission to be exempt from the provisions of this chapter or has received an exemption from the FDA pursuant to 21 C.F.R. 206.7.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-033, filed 6/1/20, effective 7/1/20.]

WAC 246-945-035 Drug sample prohibitions. (1) Except as provided in subsection (2) of this section, a pharmacy shall not possess, distribute or dispense legend drug samples.

(2) A pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request of an authorized practitioner pursuant to RCW 69.45.050 may possess, distribute or dispense legend drug samples.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-035, filed 6/1/20, effective 7/1/20.]

WAC 246-945-037 Regulated steroids. The following drugs are classified as steroids for the purposes of RCW 69.41.310. The drugs designated shall include the following and any synthetic derivatives or any isomer, ester, salt, or derivative of the following that act in the same manner on the human body:

(1) Anabolicum;
(2) Anadrol;
(3) Anatrofin;
(4) Anavar;
(5) Androxon;

(6) Andriol;
(7) Android;
(8) Bolandiol;
(9) Bolasterone;
(10) Boldenone;
(11) Boldenone undecylenate;
(12) Bolenol;
(13) Bolfortan;
(14) Bolmantalate;
(15) Cheque;
(16) Chlorotestosterone;
(17) Clostebol;
(18) Deca Durabolin;
(19) Dehydrochlormethyl-testosterone;
(20) Delatestyl;
(21) Dianabol; and
(22) Dihydrolone.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-037, filed 6/1/20, effective 7/1/20.]

WAC 246-945-038 Availability and identity of amygdalin. (1) Amygdalin (laetrile) may be manufactured and distributed through intrastate commerce in Washington in accordance with all applicable state laws and regulations.

(2) Amygdalin (laetrile) imported into the state of Washington shall be imported in conformity with federal regulations or court decisions.

(3) Under the direction of the commission batches of amygdalin (laetrile) must be made with the costs for required testing, including purity and potency, to be borne by the manufacturer and wholesale distributor. The manufacturer and wholesale distributor is responsible for the quality of the drug product, in accordance with RCW 18.64.270.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-038, filed 6/1/20, effective 7/1/20.]

WAC 246-945-040 Uniform Controlled Substance Act. (1) The commission adopts 21 C.F.R. as its own. The following sections do not apply: Sec. 1301.13, Sec. 1301.33, Sec. 1301.35-.46, Sec. 1303, Sec. 1308.41-.45, and Sec. 1316.31-.67. Any inconsistencies between 21 C.F.R. Sec. 1300 through 1321 and this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(2) Registration. A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed. Application for registration must be made on forms supplied by the commis-

sion, and all requested information must be supplied unless the information is not applicable, which must be indicated by the applicant. An applicant for registration must hold the appropriate license provided for in chapter 18.64 RCW.

(3) Recordkeeping and Inventory. Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:

(a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;

(b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;

(c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11.

(4) Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.

(5) Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.

(6) A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-040, filed 6/1/20, effective 7/1/20.]

WAC 246-945-043 Designation of nonnarcotic stimulant drugs for the purposes of RCW 69.50.402 (1)(c). The commission hereby designates, the following Schedule II controlled substances as nonnarcotic stimulants for purposes of RCW 69.50.402 (1)(c):

(1) Amphetamine sulfate in any of its generic forms.

(2) Dextroamphetamine sulfate in any of its generic forms and under the following brand names:

(a) Dexedrine (SKF);

(b) Dexedrine spansules (SKF).

(3) Dextroamphetamine HCL in any of its generic forms.

(4) Dextroamphetamine tannate in any of its generic forms.

(5) Methamphetamine HCL (Desoxyephedrine HCL) in any of its generic forms and under the following brand name: Desoxyn (Abbott).

(6) Amphetamine complex in any of its generic forms and under the following brand names:

(a) Biphetamine 12 1/2 (Pennwalt);

(b) Biphetamine 20 (Pennwalt).

(7) Combined amphetamines sold under the following brand names: Obetrol-10 and 20 (Obetrol).

(8) Phenmetrazine HCL in any of its generic forms and under the following brand name: Preludin (Boehringer-Ingelheim).

(9) Methylphenidate HCL in any of its generic forms and under the following brand name: Ritalin (Ciba).

(10) Lisdexamfetamine in any of its generic forms and under the following brand name: Vyvanse.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-043, filed 6/1/20, effective 7/1/20.]

WAC 246-945-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants. The Schedule II stimulants listed in WAC 246-945-043 may be prescribed, dispensed, or administered to patients for the following disease states or conditions:

(1) Disease states or conditions listed in RCW 69.50.402 (1)(c)(ii); and

(2) Moderate to severe binge eating disorder in adults.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-045, filed 6/1/20, effective 7/1/20.]

WAC 246-945-047 Sodium pentobarbital registration disciplinary action. In addition to any criminal or civil liabilities that may occur, the commission may deny, suspend, or revoke registration upon determination that:

(1) The registration was procured through fraud or misrepresentation;

(2) The registrant or any agent or employee of the registrant has violated any of the federal or state laws related to drugs, or has violated any of the rules or regulations of the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-047, filed 6/1/20, effective 7/1/20.]

WAC 246-945-050 Commission authority to control. Pursuant to the authority granted to the commission in RCW 69.50.201, the commission has considered the following factors with regards to each of the substances listed in this chapter and in chapter 69.50 RCW:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The risk to the public health;

(7) The potential of the substance to produce psychic or psychological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under the Uniform Controlled Substances Act (chapter 69.50 RCW).

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-050, filed 6/1/20, effective 7/1/20.]

WAC 246-945-051 Schedule I. The commission finds that the following substances have high potential for abuse and have no accepted medical use in treatment in the United States or that they lack accepted safety for use in treatment under medical supervision. In addition to the substances scheduled in RCW 69.50.204 the commission places each of the following controlled substances by whatever official name, common or usual name, chemical name, or brand name in Schedule I.

(1) Opiates. Unless specifically exempted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide); some other names: Acetyl fentanyl;

(b) 3,4-Dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers; some other names: U-47700;

(c) 3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide; some other names: AH-7921;

(d) Dextrorphan;

(e) N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers; some other names: Acryl fentanyl and acryloylfentanyl;

(f) N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers; some other names: Butyryl fentanyl;

(g) N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers; some other names: Furanyl fentanyl;

(h) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers; some other names: 4-fluoroisobutyryl fentanyl and para-fluoroisobutyryl fentanyl;

(i) N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers; some other names: Beta-hydroxythiofentanyl; and

(j) Propheptazine.

(2) Opium derivatives. Unless specifically exempted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation: Methylhydromorphine.

(3) Hallucinogenic substances. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation. For purposes of this subsection only, the term "isomer" includes the optical, position, and geometric isomers:

(a) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one; some other names: Butylone and bk-MBDB;

(b) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; some other names: Pentylone and bk-MBDP;

(c) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine; some other names: 2C-P;

(d) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine; some other names: 2C-E;

(e) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine; some other names: 2C-D;

(f) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine; some other names: 2C-N;

(g) 2-(2,5-Dimethoxyphenyl)ethanamine; some other names: 2C-H;

(h) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine; some other names: 25B-NBOMe and 2C-B-NBOMe;

(i) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine; some other names: 2C-C;

(j) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine; some other names: 25C-NBOMe and 2C-C-NBOMe;

(k) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine; some other names: 2C-I;

(l) 2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine; some other names: 25I-NBOMe and 2C-I-NBOMe;

(m) 2,5-dimethoxyamphetamine; some other names: 2,5-dimethoxy-alpha-methylphenethylamine and 2,5-DMA;

(n) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine; some other names: 2C-T-2;

(o) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine; some other names: 2C-T-4;

(p) 3,4-Methylenedioxymethcathinone; some other names: Methylone;

(q) 3,4-methylenedioxy-N-ethylamphetamine; some other names: N-ethyl-alpha-methyl-3,4(methylenedioxy)-phenethylamine, N-ethyl MDA, MDE, and MDEA;

(r) 3,4-Methylenedioxypyrovalerone; some other names: MDPV;

(s) 4-bromo-2,5-dimethoxy-amphetamine: Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; some other names: 4-bromo-2,5-DMA;

(t) 4-methoxyamphetamine; some other names: 4-methoxy-alpha-methylphenethylamine; paramethoxyamphetamine, PMA;

(u) 4-methyl-2,5-diamethoxyamphetamine;

(v) 4-methyl-2,5-dimethoxy-amphetamine; some other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP";

(w) 4-Methylmethcathinone; some other names: Mephedrone;

(x) 5-methoxy-N,N-dimethyltryptamine; some other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole and 5-MeO-DMT;

(y) Alpha-ethyltryptamine; some other names: Etryptamine; monase; a-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; a-ET; and AET;

(z) Beta-keto-N-Methylbenzodioxolylpropylamine; some other names: bk-MBDB and Butylone;

(aa) Ethylamine analog of phencyclidine; some other names: N-ethyl-1phenylcyclohexalymine, (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl)ethylamine; cyclohexamine; and PCE;

(bb) Ibogaine; some other names: 7-Ethyl-6,6 beta,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1',2':1,2] azepino [5,4-b] indole; and Tabernanthe iboga;

(cc) Marijuana Extract - Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant;

(dd) N-hydroxy-3,4-methylenedioxyamphetamine; some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)-phenethylamine; and N-hydroxy MDA;

(ee) Pyrrolidine analog of phencyclidine; some other names: 1-(1-phenylcyclohexyl)pyrrolidine; PCPy; and PHP;

(ff) Thiophene analog of phencyclidine; some other names: 1-[1-(2-thienyl)-cyclohexyl]-pipendine; 2-thienylanalog of phencyclidine; TPCP; TCP.

(4) Stimulants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(a) Cathinone; also known as 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone; 2-aminopropiophenone; and norephedrone;

(b) *N,N*-dimethylamphetamine; some other names: N,N-alpha-trimethyl-benzeneethanamine; and N,N-alpha-trimethylphenethylene.

(5) Cannabimimetic agents and synthetic cannabinoids. Any of the following synthetic cannabimimetics and cannabinoids, commonly known as spice, their salts, isomers, and salts of isomers, unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quality of the following substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) (1-pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclopropyl)methanone; some other names: UR-144;

(b) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: THJ-2201;

(c) [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone; some other names: 5-fluoro-UR-144 and XLR11;

(d) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; some other names: AM2201;

(e) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; some other names: AM694;

(f) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole; some other names: JWH-200;

(g) 1-butyl-3-(1-naphthoyl)indole; some other names: JWH-073;

(h) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole; some other names: SR-18 and RCS-8;

(i) 1-hexyl-3-(1-naphthoyl)indole; some other names: JWH-019;

(j) 1-pentyl-3-(1-naphthoyl)indole; some other names: JWH-018 and AM678;

(k) 1-pentyl-3-(2-chlorophenylacetyl)indole; some other names: JWH-203;

(l) 1-pentyl-3-(2-methoxyphenylacetyl)indole; some other names: JWH-250;

(m) 1-pentyl-3-(4-chloro-1-naphthoyl)indole; some other names: JWH-398;

(n) 1-pentyl-3-(4-methyl-1-naphthoyl)indole; some other names: JWH-122;

(o) 1-pentyl-3-[(4-methoxy)-benzoyl]indole; some other names: SR-19 and RCS-4;

(p) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole; some other names: JWH-081;

(q) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol; some other names: CP-47,497;

(r) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol; some other names: Cannabicyclohexanol or CP-47,497 C8-homolog;

(s) Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: MDMB-FUBINACA;

(t) Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: 5F-ADB; and 5F-MDMB-PINACA;

(u) Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: 5F-AMB;

(v) Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: MDMB-CHMICA; and MMB-CHMINACA;

(w) N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide; some other names: APINACA and AKB48;

(x) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: ADB-FUBINACA;

(y) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: MAB-CHMINACA; and ADB-CHMINACA;

(z) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide; some other names: ADB-PINACA;

(aa) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide; some other names: AB-FUBINACA;

(bb) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: AB-CHMINACA;

(cc) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: AB-PINACA;

(dd) N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: 5F-APINACA; and 5F-AKB48;

(ee) Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate; some other names: 5-fluoro-PB-22; and 5F-PB-22;

(ff) Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate; some other names: PB-22; and QUPIC.

(6) Synthetic cathinones, commonly known as bath salts, and its derivatives. Unless specifically exempted or listed in another schedule, any of the following synthetic cathinone and derivatives, their salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific designation:

(a) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one; some other names: Naphyrone;

(b) 2-(methylamino)-1-phenylpentan-1-one; some other names: Pentedrone;

(c) 3-fluoro-N-methylcathinone; some other names: 3-FMC;

(d) 4-fluoro-N-methylcathinone; some other names: 4-FMC and flephedrone;

(e) 4-methyl-alpha-pyrrolidinopropiophenone; some other names: 4-MePPP;

(f) 4-methyl-N-ethylcathinone; some other names: 4-MEC;

(g) Alpha-pyrrolidinobutiophenone; some other names: Alpha-PBP;

(h) Alpha-pyrrolidinopentiophenone; some other names: Alpha-PVP;

(i) N-Ethylpentylone, its optical, positional, and geometric isomers, salts, and salts of isomers; some other names: 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one).

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-051, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-945-052 Schedule II. The commission finds that the following substances have a high potential for abuse and have currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions and that the abuse of the following substances may lead to severe psychic or psychological dependence. In addition to the substances listed in RCW 69.50.206, the commission places each of the following drugs and other substances by whatever official name, common or usual name, chemical name, or brand name in Schedule II.

(1) Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including:

(a) Decocainized coca leaves or extractions which do not contain cocaine or ecgonine; or

(b) [^{123}I]ioflupane.

(2) Opiates. Unless specifically exempted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene exempted: Thiafentanil.

(3) Hallucinogenic substances.

(a) Dronabinol[(-)-delta-9-trans tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration;

(b) Nabilone; some other names: (±)-trans-3-(1,1-dimethlheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzol[b,d]pyran-9-one.

(4) Immediate precursors. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances: Immediate precursor to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP).

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-052, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-945-053 Schedule II immediate precursors. The commission finds and designates the following substances as being the principal compound used or produced primarily for use and which are an immediate chemical intermediary used or likely to be used, in the manufacture of a Schedule II controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

(1) Unless specifically exempted or listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances or their salts or isomers having potential for abuse associated with the preparation of controlled substances shall be a Schedule II controlled substance.

(a) Anthranilic acid;

(b) Ephedrine;

(c) Hydriodic acid;

(d) Methylamine;

(e) Phenylacetic acid;

(f) Pseudoephedrine;

(g) Methephedrine;

(h) Lead acetate; and

(i) Methyl formamide.

(2) Any drug or compound containing ephedrine, or any of its salts or isomers, or pseudoephedrine, or any of its salts or isomers that are prepared for dispensing or over-the-counter distribution and are in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations are not controlled substances for the purpose of this section.

(3) Any cosmetic containing lead acetate that is distributed in compliance with the Federal Food, Drug and Cosmetic Act and applicable regulations are not controlled substances.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-053, filed 6/1/20, effective 7/1/20.]

WAC 246-945-054 Schedule III. The commission finds that the following substances have a potential for abuse less than the substances listed in Schedule I under RCW 69.50.204 and WAC 246-945-051 and Schedule II under RCW 69.50.206 and WAC 246-945-052, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to moderate or low physical dependency or high psychological dependency. In addition to substances listed in RCW 69.50.208, the commission places each of the following drugs and other substances by whatever official name, common or usual name, chemical name, or brand name in Schedule III.

(1) Depressants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system: Perampanel, and its salts, isomers, and salts of isomers.

(2) Anabolic steroids. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids that promotes muscle growth, and includes:

(a) 17alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane;

(b) 17alpha-methyl-3beta,17beta-dihydroxy-5alpha-androstane;

(c) 17alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one) some other names: '17-alpha-methyl-1-testosterone';

(d) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-dine-3,17-dione);

(e) Norandrostenediol:

(i) 19-nor-4-androstenediol (3alpha, 17beta-dihydroxyestr-4-ene);

(ii) 19-nor-4-androstenediol (3beta, 17beta-dihydroxyestr-4-ene);

(iii) 19-nor-5-androstenediol (3beta, 17beta-dihydroxyestr-5-ene);

(iv) 19-nor-5-androstenediol (3alpha, 17beta-dihydroxyestr-5-ene).

(f) Norandrostenedione:

(i) 19-nor-4-androstenedione (estr-4-en-3,17-dione);

(ii) 9-nor-5-androstenedione (estr-5-en-3,17-dione).

(g) Androstanediol:

(i) 3alpha,17beta-dihydroxy-5alpha-androstane;

(ii) 3beta,17beta-dihydroxy-5alpha-androstane.

(h) Boldione (androsta-1,4-dine-3,17-dione);

(i) Desoxymethyltestosterone (17alpha-methyl-5alpha-androst-2-en-17beta-ol); some other names: 'madol'.

(j) Mestanolone (17alpha-methyl-17beta-hydroxy-5alpha-androstan-3-one);

(k) Methasterone (2alpha,17alpha-dimethyl-5alpha-androstan-17beta-ol-3-one);

(l) Prostanozol (17beta-hydroxy-5alpha-androstano[3,2-c]pyrazole).

(m) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of health and human services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subsection.

(3) Exempt anabolic steroid products. The following anabolic steroid products in Table A of this subsection containing compounds, mixtures, or preparations are exempt from the recordkeeping, refill restrictions, and other Controlled Substances Act requirements:

Table A

Trade Name	Company	Form	Ingredients	Quantity
Andro-Estro 90-4	Rugby Laboratories, Rockville Centre, NY	Vial	Testosterone enanthate; Estradiol valerate	90 mg/mL; 4 mg/mL
Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO	Vial	Testosterone enanthate; Estradiol valerate	90 mg/mL; 4 mg/mL
Component E-H in process granulation	Ivy Laboratories, Inc., Overland Park, KS	Pail or drum	Testosterone propionate; Estradiol benzoate	10 parts; 1 part
Component E-H in process pellets	Ivy Laboratories, Inc., Overland Park, KS	Pail	Testosterone propionate; Estradiol benzoate	25 mg/2.5 mg/ pellet
Component TE-S in process granulation	Ivy Laboratories, Inc., Overland Park, KS	Pail or drum	Trenbolone acetate; Estradiol USP	5 parts; 1 part
Component TE-S in process pellets	Ivy Laboratories, Inc., Overland Park, KS	Pail	Trenbolone acetate; Estradiol USP	120 mg/24 mg/pellet
depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Depo-Testadiol	The Upjohn Company, Kalamazoo, MI	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
DEPTO-T.E.	Quality Research Pharm., Carmel, IN	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Duomone	Wintec Pharmaceutical, Pacific, MO	Vial	Testosterone enanthate; Estradiol valerate	90 mg/mL; 4 mg/mL
DUO-SPAN II	Primedics Laboratories, Gardena, CA	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
DURATESTRIN	W. E. Hauck, Alpharetta, GA	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Essian	Pharmaceutics International Inc., Hunt Valley, MD	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg
Essian H.S.	Pharmaceutics International Inc., Hunt Valley, MD	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg)	Interpharm, Inc.	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg)	Interpharm, Inc.	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg

Trade Name	Company	Form	Ingredients	Quantity
Esterified Estrogens/ Methyltestosterone, (0.625 mg/1.25 mg) Tablet	ANDAPharm, LLC	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
Esterified Estrogens/ Methyltestosterone, (1.25 mg/2.5 mg) Tablet	ANDAPharm, LLC	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg
Estratest	Solvay Pharmaceuticals, Marietta, GA	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg
Estratest H.S.	Solvay Pharmaceuticals, Marietta, GA	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
Masculinizing Feed for Fish (Investigational)	Rangen, Inc., Buhl, ID	Plastic Bags	Methyltestosterone	60 mg/kg fish feed
Menogen	Sage Pharmaceuticals, Shreveport, LA	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg
Menogen H.S.	Sage Pharmaceuticals, Shreveport, LA	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg)	Lannett Company, Inc.	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg
Methyltestosterone and Esterified Estrogens (Half Strength) (1.25 mg/0.625 mg)	Lannett Company, Inc.	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
PAN ESTRA TEST	Pan American Labs; Covington, LA	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Premarin with Methyltestosterone	Ayerst Labs Inc., New York, NY	TB	Conjugated estrogens; Methyltestosterone	0.625 mg; 5.0 mg
Premarin with Methyltestosterone	Ayerst Labs Inc., New York, NY	TB	Conjugated estrogens; Methyltestosterone	1.25 mg; 10.0 mg
Synovex H in-process bulk pellets	Syntex Animal Health, Palo Alto, CA	Drum	Testosterone propionate; Estradiol benzoate	25 mg; 2.5 mg/pellet
Synovex H in-process granulation	Syntex Animal Health, Palo Alto, CA	Drum	Testosterone propionate; Estradiol benzoate	10 parts; 1 part
Synovex Plus in-process bulk pellets	Fort Dodge Animal Health, Fort Dodge, IA	Drum	Trenbolone acetate; Estradiol benzoate	25 mg; 3.5 mg/pellet
Synovex Plus in-process granulation	Fort Dodge Animal Health, Fort Dodge, IA	Drum	Trenbolone acetate; Estradiol benzoate	25 parts; 3.5 parts
Syntest D.S.	Syntho Pharmaceuticals, Inc.	TB	Esterified estrogens; Methyltestosterone	1.25 mg; 2.5 mg
Syntest H.S.	Syntho Pharmaceuticals, Inc.	TB	Esterified estrogens; Methyltestosterone	0.625 mg; 1.25 mg
TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Testoderm 4 mg/d	Alza Corp., Palo Alto, CA	Patch	Testosterone	10 mg
Testoderm 6 mg/d	Alza Corp., Palo Alto, CA	Patch	Testosterone	15 mg
Testoderm in-process film	Alza Corp., Palo Alto, CA	Sheet	Testosterone	0.25 mg/cm^2
Testoderm with Adhesive 4 mg/d	Alza Corp., Palo Alto, CA	Patch	Testosterone	10 mg
Testoderm with Adhesive 6 mg/d	Alza Corp., Palo Alto, CA	Patch	Testosterone	15 mg
Testoderm with Adhesive in-process film	Alza Corp., Palo Alto, CA	Sheet	Testosterone	0.25 mg/cm^2

Trade Name	Company	Form	Ingredients	Quantity
Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate, Amityville, NY	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Testosterone Cypionate/ Estradiol Cypionate Injection	Best Generics, North Miami Beach, FL	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Testosterone Cypionate/ Estradiol Cypionate Injection	Goldline Labs, Ft. Lauderdale, FL	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Testosterone Cypionate/ Estradiol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL
Testosterone Cypionate/ Estradiol Cypionate Injection	Steris Labs Inc., Phoenix, AZ	Vial	Testosterone cypionate; Estradiol cypionate	50 mg/mL; 2 mg/mL

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-054, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-945-055 Schedule IV. The commission finds that the following substances have a low potential for abuse relative to substances in Schedule III under RCW 69.50.208 and WAC 246-945-054, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III. In addition to substances listed in RCW 69.50.210, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule IV.

(1) Narcotic drugs. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set in this subsection: 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol).

(2) Depressants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Alfaxalone;

(b) Fospropofol;

(c) Suvorexant.

(3) Any material, compound, mixture, or preparation which contains any quantity of Lorcaserin, including its salts, isomers, and salts of such isomers, wherever the existence of such salts, isomers, and salts of isomers is possible.

(4) Stimulants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation

which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Cathine ((+) - norpseudoephedrine);

(b) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(5) Other substances. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts: Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-055, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-945-056 Schedule V. The commission finds that the following substances have low potential for abuse relative to substances in Schedule IV under RCW 69.50.210 and WAC 246-945-055 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule V.

Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Brivaracetam ((2S)-2-((4R)-2-oxo-4-propylpyrrolidin-1-yl) butanamide); also referred to as BRV; UCB-34714; Briviact;

(2) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester].

[Statutory Authority: RCW 18.64.005 and 69.50.201. WSR 22-10-044, § 246-945-056, filed 4/28/22, effective 5/29/22. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-056, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

WAC 246-945-060 Other controlled substance registrants—Requirements. (1) All persons and firms, except persons exempt from registration, must register with the commission in order to legally possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers will be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-945-053.

(3) The applicant for a controlled substance registration must complete and return an application form supplied by the commission. A list of the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances must be listed on the application or on an addendum.

(4) All controlled substances must be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. The registrant shall inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuances of the registration and shall maintain the inventory list for two years. The registrant shall return unwanted, outdated, or unusable controlled substances to the source from which it was obtained or surrendered to the DEA.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-060, filed 6/1/20, effective 7/1/20.]

WAC 246-945-063 Precursor definitions. The definitions in this section apply to WAC 246-945-065 through 246-945-088.

(1) "Registered product" means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(2) "Retailer" means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(3) "Sale" means the transfer, selling, or otherwise furnishing of any restricted product to any person.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-063, filed 6/1/20, effective 7/1/20.]

WAC 246-945-065 Precursor substance control. (1) For the purpose of this chapter, in addition to the substances in RCW 69.43.010, a precursor substance is any of the following substances or their salts or isomers:

(a) Gamma-butyrolactone (GBL); and

(b) Hydriodic acid.

(2) A precursor substance defined in subsection (1) of this section does not include any drug that contains ephedrine, phenylpropanolamine, or pseudoephedrine or any cosmetic if that drug or cosmetic can be lawfully sold, transferred, or furnished over-the-counter without a prescription or by a prescription under chapter 69.04 or 69.41 RCW.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-065, filed 6/1/20, effective 7/1/20.]

WAC 246-945-070 Reports of precursor receipt. (1) Any manufacturer, wholesaler, retailer, or any other person who receives from any source outside the state of Washington any precursor substance listed in WAC 246-945-065 or RCW 69.43.010 shall submit a report of such transaction within fourteen days of the receipt of that substance.

(2) The report shall contain the following information:

(a) Name of substance;

(b) Quantity received;

(c) Date received;

(d) Name and address of firm or person receiving substance; and

(e) Name and address of the source selling, transferring, or furnishing the substance.

(3) The report shall be on a form approved by the commission. In lieu of an approved form the commission will accept a copy of an invoice, packing list, or other shipping document which contains the information in subsection (2) of this section. Under this option purchase price information appearing on the document can be deleted.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-070, filed 6/1/20, effective 7/1/20.]

WAC 246-945-072 Precursor substance monthly reporting. (1) A permit holder who regularly transfers the same precursor substance to the same recipient may apply to the commission for authorization to submit the report of said transactions on a monthly basis. Requests for monthly reporting authorization must be received at the commission office at least thirty days prior to the commission meeting at which the request will be considered. The commission will review each request to determine if the requirements of RCW 69.43.010(4), are met and will notify the permit holder of its decision and the reporting format that will be authorized.

(2) A permit holder may also petition the commission to accept the monthly report on a computer-generated basis. The report may be furnished in hard copy, on commission-approved data storage methods or by computer interface with a commission-operated computer. The permit holder is responsible for the accuracy of the report and the prompt correction of any data entry or transmission errors.

(3) The authorization to use monthly reports or computer-generated monthly reports may be rescinded at the commission's discretion and with thirty days' notice.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-072, filed 6/1/20, effective 7/1/20.]

WAC 246-945-075 Suspicious transactions and reporting requirements. (1) A manufacturer, wholesaler or distributor who sells, transfers, or furnishes a regulated product to any licensee shall report any suspicious transaction in writing to the commission.

(2) For the purpose of this rule, a regulated product is defined as a product specified in RCW 69.43.010(1) or WAC 246-945-065.

(3) For the purposes of this rule, a "suspicious transaction" is defined as any sale or transfer that meets any of the following criteria:

(a) Any sale or transfer that would lead a reasonable person to believe that the substance is likely to be used for the purpose of unlawfully manufacturing a controlled substance under chapter 69.50 RCW, based on such factors as:

(i) The amount of the substance involved;

(ii) The method of payment;

(iii) The method of delivery; or

(iv) Any past dealings with any participant in the transaction.

(b) Any sale or transfer involving payment for a regulated product in cash or money orders in a total amount of more than two hundred dollars.

(c) Any sale or transfer of a regulated product that meets the criteria identifying suspicious orders in the U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Program Report of the Suspicious Orders Task Force. Copies of the publication are available upon request from the commission.

(d) Any individual sale or transfer of a regulated product that exceeds ten percent of the nonprescription drugs contained in the order.

(e) Any order which contains regulated products and has no additional nonprescription drugs is considered a suspicious transaction.

(4) The written report of a suspicious transaction shall contain, at a minimum, the following information:

(a) Name, address, and phone number of the manufacturer and/or wholesaler making the report;

(b) Washington state license number of the wholesaler;

(c) Washington state unified business identifier (UBI) number of the recipient of the suspicious transaction;

(d) Trade/brand name of regulated product;

(e) Generic name of regulated product's active ingredients;

(f) Name, address and phone number of the recipient of the suspicious transaction;

(g) Quantity of substance purchased, transferred, or furnished, by number of units and doses per unit;

(h) Date of purchase or transfer;

(i) Method of payment of the substance;

(j) Lot number if available; and

(k) National Drug Code number if available.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-075, filed 6/1/20, effective 7/1/20.]

WAC 246-945-077 Precursor substance requirements for the sale of a restricted product. Unless exempted in RCW 69.43.110, a retailer must:

(1) Verify the purchaser's identity by means of acceptable identification as defined in this chapter;

(2) Ensure that the purchaser is at least eighteen years of age; and

(3) Record all of the information required in WAC 246-945-078 in the record of transaction before completing the sale.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-077, filed 6/1/20, effective 7/1/20.]

WAC 246-945-078 Record of sales—Electronic methamphetamine precursor tracking. (1) Unless granted an exemption under RCW 69.43.110 upon the sale or attempted sale of a restricted product, each retailer shall enter and electronically transmit the following information to the methamphetamine precursor tracking system prior to completion of the transaction:

(a) Sale transaction information including:

(i) Date and time of the intended purchase;

(ii) Product description;

(iii) Quantity of product to be sold including:

(A) Total grams of restricted product per box;

(B) Number of boxes per transaction.

(b) Purchaser's information including:

(i) Full name as it appears on the acceptable identification;

(ii) Date of birth;

(iii) The address as it appears on the photo identification or the current address if the form of photo identification used does not contain the purchaser's address. The address information must include the house number, street, city, state, and zip code;

(iv) Form of photo identification presented by the purchaser, including the issuing agency of the acceptable identification, and the identification number appearing on the identification; and

(v) Purchaser's signature. If the retailer is not able to secure an electronic signature, the retailer shall maintain a hard copy of a signature logbook consisting of each purchaser's signature and the transaction number provided by the methamphetamine precursor tracking system.

(c) The full name or initials of the individual conducting the transaction; and

(d) Other information as required by the methamphetamine precursor tracking system database.

(2) If a transaction occurs during a time when the methamphetamine precursor tracking system is temporarily unavailable due to power outage or other technical difficulties, the retailer shall record the information required in this section in a written logbook for entry into the methamphetamine precursor tracking system within seventy-two hours of the system becoming operational.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-078, filed 6/1/20, effective 7/1/20.]

WAC 246-945-080 Acceptable forms of identification. Acceptable forms of identification are defined as current foreign, federal, state, or tribal government-issued identification which include the person's photograph, name, date of birth, signature, and physical description. Acceptable forms of identification include, but are not limited to:

(1) A valid driver's license or instruction permit issued by any U.S. state or foreign government. If the purchaser's driver's license has expired, he or she must also show a valid temporary driver's license with the expired card.

(2) A United States Armed Forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.

(3) A merchant marine identification card issued by the United States Coast Guard.

(4) An identification card issued by any foreign, federal, or state government.

(5) An official U.S. passport or an unexpired foreign passport that contains a temporary I-551 stamp.

(6) An enrollment card issued by the governing authority of a federally recognized Indian tribe located in Washington state, if the enrollment card incorporates security features comparable to those implemented by the department of licensing for Washington state drivers' licenses.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-080, filed 6/1/20, effective 7/1/20.]

WAC 246-945-085 Maintenance of and access to retail sales records of restricted products. (1) The retail sales records required under WAC 246-945-078 are confidential and accessible by the commission and law enforcement agencies. Law enforcement may access the retail sales records for criminal investigations when, at a minimum, there is an articulated individualized suspicion of criminal activity.

(2) Each law enforcement agency's administrator, chief, sheriff, or other chief executive officer shall ensure:

(a) Only authorized employees have access to the databases;

(b) Each employee use his or her unique password or access code to access the databases;

(c) Each employee adheres to all state and federal laws regarding confidentiality; and

(d) As employees change, new passwords or access codes are assigned to new employees and passwords of ex-employees or transferred employees are removed.

(3) Retail sales records of restricted products, electronic or written, must be kept for a minimum of two years.

(4) Retail sales records must be destroyed in a manner that leaves the record unidentifiable and nonretrievable.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-085, filed 6/1/20, effective 7/1/20.]

WAC 246-945-087 Exemptions from electronic reporting. (1) Pharmacies are exempt from entering purchase information into the methamphetamine precursor tracking system when the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine or their salts or isomers, or salts of isomers is sold pursuant to a prescription written by an authorized practitioner.

(2) A retailer must demonstrate "good cause" to qualify for an exemption from electronic reporting requirements. "Good cause" includes, but is not limited to, situations where the installation of the necessary equipment to access the methamphetamine precursor tracking system is unavailable or cost prohibitive to the retailer.

(a) A retailer must submit a written request on a form provided by the commission, which shall include the following information:

(i) The reason for the exemption; and

(ii) The anticipated duration needed for the exemption.

(b) An exemption from electronic reporting may not exceed one hundred eighty days.

(c) A retailer may request additional exemptions by submitting a form defined in this subsection at least thirty days before the current exemption expires. The retailer must show that compliance will cause the business significant hardship.

(d) For all sales transactions involving the sale or attempted sale of a restricted product occurring during the period of an exemption, the retailer shall record into a written logbook, at the time of the sale or attempted sale, the information required under WAC 246-945-078(1).

(e) The written logbook of each sale or attempted sale shall be available for inspection by any law enforcement officer or commission inspector during normal business hours.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-087, filed 6/1/20, effective 7/1/20.]

WAC 246-945-088 Denial of a sale—Override. (1) The retailer must deny the sale of restricted product to purchasers who are not able to produce acceptable identification or if the sale would violate RCW 69.43.110 or federal law.

(2) In the event that the retailer perceives that refusal of the purchase may place them in imminent physical harm, the retailer may use the database safety override function to proceed with the sale, provided that when the threat is no longer perceived, the retailer must immediately contact local law enforcement to report the incident.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-088, filed 6/1/20, effective 7/1/20.]

Subpart D – Home Dialysis

WAC 246-945-090 Home dialysis program—Legend drugs. Pursuant to RCW 18.64.257 and 69.41.032, a medicare-approved dialysis center or facility operating a medicare-approved home dialysis program may sell, deliver, possess or dispense directly to its home dialysis patients in cases or full shelf package lots, if prescribed by a physician, the following legend drugs:

(1) Sterile heparin, 1000 u/mL, in vials;

(2) Sterile potassium chloride, 2 mEq/mL, for injection;

(3) Commercially available dialysate; and

(4) Sterile sodium chloride, 0.9%, for injection in containers of not less than 150 mL.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-090, filed 6/1/20, effective 7/1/20.]

WAC 246-945-091 Home dialysis program—Pharmacist consultant. Home dialysis programs involved in the distribution of legend drugs as permitted by RCW 18.64.257 and 69.41.032, shall have an agreement with a pharmacist which provides for consultation as necessary. This shall include advice on the drug distribution process to home dialysis patients and on the location used for storage and distribution of the authorized drugs, which shall be reasonably separated from other activities and shall be secure.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-091, filed 6/1/20, effective 7/1/20.]

WAC 246-945-092 Home dialysis program—Records. (1) A record of shipment shall be attached to the prescriber's order and shall include:

(a) The name of the patient;

(b) Strengths and quantities of drugs;

(c) The manufacturers' names;

(d) Date of shipment;

(e) Names of persons who selected, assembled and packaged for shipment; and

(f) The name of the pharmacist or designated individual responsible for the distribution.

(2) Prescription and drug distribution records shall be maintained in accordance with WAC 246-945-020.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-092, filed 6/1/20, effective 7/1/20.]

WAC 246-945-093 Home dialysis program—Quality assurance. Home dialysis programs involved in the distribution of legend drugs as permitted by RCW 18.64.257 and 69.41.032, shall develop a quality assurance program for drug distribution and shall maintain records of drug distribution errors and other problems, including loss due to damage or theft.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-093, filed 6/1/20, effective 7/1/20.]

Subpart E - Compounding

WAC 246-945-100 Compounding minimum standards. (1) All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration:

(a) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations;

(b) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations;

(c) USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings; and

(d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) Copies of the USP General Chapters listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road

S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-100, filed 6/1/20, effective 7/1/20.]

PART 2 – GENERAL LICENSING

WAC 246-945-145 License required. An individual providing pharmacy services to individuals located in Washington is required to be credentialed by the commission, unless the individual is providing pharmacy services within the scope of their employment, or affiliation, with a Washington licensed nonresident pharmacy or the law otherwise permits the practice.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-145, filed 6/1/20, effective 7/1/20.]

WAC 246-945-150 Applicable forms. All applications for initial licensure and renewals must be submitted on forms provided by the commission as well as any other required documentation.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-150, filed 6/1/20, effective 7/1/20.]

Subpart A – Pharmacy Interns and Pharmacist

WAC 246-945-155 Pharmacy interns—Registration requirements. (1) Unless otherwise stated, each individual shall register with the commission, as a pharmacy intern before beginning pharmacy practice experiences in Washington state. The commission shall grant a registration to practice pharmacy as a pharmacy intern to an individual who is:

(a) Currently enrolled in a professional degree program of a commission accredited school or college of pharmacy and making satisfactory progress towards meeting the requirements for licensure as a pharmacist;

(b) A graduate of a commission accredited school or college of pharmacy;

(c) A graduate of a school or college of pharmacy located outside the United States who has established educational equivalency by obtaining certification by FPGEC;

(d) Required by the commission to be an intern because the commission has determined the individual needs to complete additional practical experience before a pharmacist license is issued or reissued; or

(e) An out-of-state pharmacist enrolled in or participating in an established residency program.

(2) A pharmacy intern shall practice under the immediate supervision of a licensed pharmacist except in accordance with RCW 18.64.253.

(3) A pharmacy intern registration can only be renewed twice.

(4) The commission may consider a pharmacy intern registration inoperable or superseded if one of the following occurs:

(a) A pharmacy intern has not graduated from and is no longer enrolled or in good standing with a commission accredited school or college of pharmacy.

(b) A pharmacy intern is issued a license to practice as a pharmacist in Washington state or another U.S. jurisdiction.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-155, filed 6/1/20, effective 7/1/20.]

WAC 246-945-156 Pharmacy intern—Temporary practice permit. (1) An individual that holds a pharmacy intern registration in another U.S jurisdiction, that has registration standards substantially equivalent to Washington, may request a temporary practice permit if:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any state;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) The applicant meets WAC 246-945-155 (1)(a) or (b).

(2) To request a temporary practice permit, the pharmacy intern applicant shall submit a written request for a temporary practice permit, and any applicable fees in accordance with chapter 246-907 WAC.

(3) A temporary practice permit expires:

(a) When the pharmacy intern registration is issued;

(b) When a notice of decision on the pharmacy intern registration application is mailed to the applicant; or

(c) Ninety days after the temporary practice permit is issued. The applicant may obtain a one-time extension of up to ninety days with approval of the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-156, filed 6/1/20, effective 7/1/20.]

WAC 246-945-162 Pharmacist license qualifications. (1) In addition to the requirements in RCW 18.64.080, an applicant for a pharmacist license who holds a baccalaureate degree in pharmacy or a doctor of pharmacy degree from a commission accredited school or college of

pharmacy shall submit documentation of education and practice experience as follows:

(a) An applicant who graduated before July 1, 2020, whose official transcripts confer or award a baccalaureate of pharmacy or doctorate of pharmacy degree shall provide certification of at least 1,500 pharmacy internship hours in accordance with WAC 246-945-163.

(b) An applicant who graduates after July 1, 2020, whose official transcripts confer or award a doctorate of pharmacy is deemed to have satisfied the pharmacy practice experience and education requirements for licensure without documentation of internship hours.

(2) An applicant for a pharmacist license whose academic training in pharmacy is from institutions in foreign countries shall:

(a) Achieve certification by FPGEC including:

(i) Passing FPGEE;

(ii) Passing required TOEFL iBT;

(b) Provide official transcripts or diploma that shows a baccalaureate of pharmacy or doctorate of pharmacy degree is awarded or conferred; and

(c) Certification of a minimum of 1,500 pharmacy internship hours in accordance with WAC 246-945-163.

(3) An applicant for a pharmacist license shall take and pass pharmacist licensure examinations as defined in WAC 246-945-165.

[Statutory Authority: RCW 18.64.005, 18.64A.020, and 18.64A.030. WSR 23-09-062, § 246-945-162, filed 4/18/23, effective 5/19/23. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-162, filed 6/1/20, effective 7/1/20.]

WAC 246-945-163 Certification of internship hours. Hours reported to the commission under WAC 246-945-162, 246-945-173, and 246-945-175, shall occur as follows:

(1) Hours must be completed within eighteen months from the date of graduation;

(2) From a commission accredited school or college of pharmacy, U.S. jurisdiction board or commission or the supervising pharmacist at the internship site;

(3) Hours shall be reported thirty days after the completion of any internship experience;

(4) The documentation must include the supervising pharmacist's evaluation and certification of internship hours, and an intern site evaluation;

(5) If the report of hours submitted to the commission indicates that the intern has not adequately performed the practice of pharmacy, the commission may reject all or part of the hours reported.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-163, filed 6/1/20, effective 7/1/20.]

WAC 246-945-165 Pharmacist licensure and jurisprudence examinations. (1) Upon authorization by the commission or its designee, an individual applying for a pharmacist license shall take and pass a pharmacy licensure examination and jurisprudence examination approved by the commission.

(2) A score of seventy-five or higher is required to pass each of the examinations.

(3) An individual who fails the licensure examination or jurisprudence examination three times shall not be authorized for further examination until they have satisfactorily completed a study or tutorial program approved by the commission.

(4) An applicant for a pharmacist license who has passed an approved licensure examination in another state may transfer their score to Washington to meet the commission's requirement to take and pass a commission approved pharmacy licensure examination if:

(a) The applicant meets the requirements in WAC 246-945-162; and

(b) The applicant completes the application process to receive a pharmacist license before the score transfer expires. The score transfer application will expire one year from the date the department receives the score transfer application.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-165, filed 6/1/20, effective 7/1/20.]

WAC 246-945-170 Pharmacist licensure by license transfer—Temporary practice permits. (1) An individual who holds an active pharmacist license, in good standing, issued by another U.S. jurisdiction may apply for a pharmacist license in Washington by license transfer. In addition to the completion of the commission's application, the applicant must:

(a) File for license transfer using the NABP eLTP process; and

(b) Take and pass the approved jurisprudence examination.

(2) A temporary practice permit to practice pharmacy may be issued to an applicant for a pharmacist license by license transfer if the applicant meets all of the requirements and qualifications in subsection (1) of this section, and the following criteria are met:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any U.S. jurisdiction;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) To request a temporary practice permit, the applicant shall submit a written request for a temporary practice permit, and pay the applicable fees in accordance with chapter 246-907 WAC.

(3) A temporary practice permit expires:

(a) When the pharmacist license is issued;

(b) When a notice of decision on the pharmacist license application is mailed to the applicant; or

(c) One hundred eighty days after the temporary practice permit is issued. The applicant may obtain a one-time extension of one hundred eighty days with approval of the commission.

(4) A temporary practice permit holder cannot qualify as a responsible pharmacy manager.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-170, filed 6/1/20, effective 7/1/20.]

WAC 246-945-171 Retired active pharmacist license status. (1) A pharmacist may apply for a retired active pharmacist license status if they:

(a) Hold an active pharmacist license issued by the commission under chapter 18.64 RCW that is in good standing;

(b) Submit an application on a form provided by the commission; and

(c) Pay the retired credential status application fee as specified in WAC 246-945-990.

(2) A pharmacist with a retired active pharmacist license status shall practice only in emergent or intermittent circumstances.

(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

(b) "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) A pharmacist with a retired active pharmacist license status must meet the continuing education requirements in WAC 246-945-178.

(4) A pharmacist with a retired active pharmacist license status must renew their license every two years in compliance with WAC 246-12-130 and pay the retired active credential status renewal fee set in WAC 246-945-990.

(5) A pharmacist with a retired active pharmacist license status must meet the requirements in WAC 246-12-140 to return their license to active status and pay the active renewal fee set in WAC 246-945-990.

[Statutory Authority: RCW 18.64.005 and 18.64.205. WSR 23-07-058, § 246-945-171, filed 3/9/23, effective 4/9/23.]

WAC 246-945-173 Expired pharmacist license. To return to active status a pharmacist with an expired license shall pay the applicable fees in accordance with chapter 246-907 WAC and:

(1) If the pharmacist license has been expired for less than three years the pharmacist shall meet the requirements of chapter 246-12 WAC, Part 2 and fifteen CPE hours per year the license has been expired.

(2) If the pharmacist license has been expired for three years or more, and the pharmacist holds an active credential in another U.S. jurisdiction, and is in good standing, the pharmacist shall:

(a) Meet the requirements in chapter 246-12 WAC, Part 2;

(b) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(c) Submit verification of current active pharmacy practice from another U.S. jurisdiction; and

(d) Take and pass the commission approved jurisprudence examination.

(3) If a pharmacist license has been expired for three years or more, and the pharmacist has not been in active practice in another U.S. jurisdiction, the pharmacist shall:

(a) Meet the requirements of chapter 246-12 WAC, Part 2;

(b) Serve an internship of three hundred hours in compliance with WAC 246-945-163; and

(c) Take and pass the commission approved jurisprudence and licensure examinations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-173, filed 6/1/20, effective 7/1/20.]

WAC 246-945-175 Inactive pharmacist license. (1) A pharmacist may obtain an inactive license by meeting the requirements of WAC 246-12-090 and RCW 18.64.140.

(2) An inactive license can be renewed in accordance with chapter 246-907 WAC.

(3) If a license is inactive for three years or less, to return to active status a pharmacist shall meet the requirements of chapter 246-12 WAC, Part 4.

(4) If a license is inactive for more than three years, and the pharmacist has been in active practice in another U.S. jurisdiction, to return to active status the pharmacist must:

(a) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(b) Submit verification of current active pharmacy from another U.S. jurisdiction;

(c) Meet the requirements of chapter 246-12 WAC, Part 4; and

(d) Take and pass the commission approved jurisprudence examination.

(5) If a pharmacist license has been inactive for more than three years, and the pharmacist has not been in active practice in another U.S. jurisdiction, to return to active status, the pharmacist shall comply with the requirements of WAC 246-945-173(3).

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-175, filed 6/1/20, effective 7/1/20.]

WAC 246-945-178 Pharmacist continuing education. (1) As part of the process to renew a pharmacist license, a pharmacist shall complete CPE in compliance with this section.

(2) A pharmacist shall complete the equivalent of 3.0 of CPE hours (equal to thirty contact hours) administered by an ACPE accredited provider each license renewal cycle.

(3) A pharmacist shall register with a program designated by the commission for tracking completed CPE hours.

(4) A pharmacist shall complete a one-time training in suicide screening and referral by the end of the first full renewal cycle after initial licensure. The training must meet the following requirements:

(a) Be at least three hours long;

(b) Be from the department of health's model list of approved suicide prevention training programs, and include content related to imminent harm via lethal means; and

(c) The hours spent completing the training in this subsection may count toward meeting CPE requirements.

(5) CPE hours cannot be carried over to the next renewal cycle.

[Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 21-04-145, § 246-945-178, filed 2/3/21, effective 12/1/21. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-178, filed 6/1/20, effective 3/1/21.]

WAC 246-945-180 Nuclear pharmacist endorsement. To receive a nuclear pharmacist endorsement, a pharmacist must:

(1) Be licensed to practice in Washington;

(2) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with WAC 246-240-075 and submit to the commission proof of compliance; and

(3) Receive a letter of recognition as a nuclear pharmacist from the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-180, filed 6/1/20, effective 7/1/20.]

Subpart B – Pharmacy Assistants and Technicians

WAC 246-945-200 Pharmacy assistants. (1) To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of WAC 246-12-020.

(2) The supervising pharmacist, shall instruct the pharmacy assistant regarding their scope of practice.

(3) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with WAC 246-945-990.

[Statutory Authority: RCW 18.64.005, 18.64A.020, and 18.64A.030. WSR 23-09-062, § 246-945-200, filed 4/18/23, effective 5/19/23. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044,

18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-200, filed 6/1/20, effective 7/1/20.]

WAC 246-945-203 Pharmacy technician-in-training authority for experiential training. (1) An individual who is enrolled in a commission-approved pharmacy-technician training program shall obtain an endorsement for experiential training in a pharmacy for:

(a) Initial certification; or

(b) As required by the commission to complete additional practice experience before a pharmacy technician certification is issued, renewed, or reactivated.

(2) An individual with a technician in training endorsement may only work in that capacity at those sites identified on the application.

(3) Before beginning the pharmacy-technician training program the individual shall submit an application to the commission to become certified as a pharmacy assistant. The application must include verification of enrollment in a commission-approved pharmacy-technician education and training program.

(4) The commission may consider the pharmacy technician-in-training authority inoperable or superseded if one of the following occurs:

(a) A pharmacy technician certification is issued;

(b) A pharmacy technician-in-training is no longer enrolled or in good standing with a commission-approved training program; or

(c) A pharmacy technician-in-training does not complete a training program within two years of entering a technician-in-training program, unless otherwise authorized by the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-203, filed 6/1/20, effective 7/1/20.]

WAC 246-945-205 Pharmacy technician certification. (1) An applicant for a pharmacy technician certification shall be 18 years of age and hold a high school diploma or GED.

(2) To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020, and:

(a) Provide proof of completion of eight hours of guided study of Washington state and federal pharmacy law. The law study shall be done in coordination and oversight of a Washington licensed pharmacist.

(b) Provide proof of successful completion of a commission-approved pharmacy-technician training program WAC 246-945-215. Acceptable documentation includes:

(i) On-the-job training program. Successful completion of didactic and practice experience signed by the program director on a form provided by the commission; or

(ii) Formal academic or college programs. Official transcripts of completion of a diploma or certificate program at a pharmacy technician school or a two-year associate degree program, which shall include evidence of practice training hours; or

(iii) Certificate of Release or Discharge from Active Duty, DD214 documenting evidence of pharmacy technician training provided by a branch of the federal armed services.

(c) Pass a national certification examination approved by the commission within one year of completing a commission-approved training program and applying for certification, unless otherwise authorized by the commission.

(3) An applicant who is a graduate of a foreign school, university or college of pharmacy or medicine, whose professional degree program is approved by the commission shall complete the following:

(a) If English is not the primary language, the applicant shall take and pass TOEFL iBT;

(b) Complete 525 hours of supervised experience under the supervision of a licensed pharmacist with training hours reported using forms provided by the commission; and

(c) Pass a national certification examination approved by the commission.

(4) An out-of-state pharmacy technician applicant must meet the same requirements as a pharmacy technician trained in Washington state.

[Statutory Authority: RCW 18.64.005, 18.64A.020, and 18.64A.030. WSR 23-09-062, § 246-945-205, filed 4/18/23, effective 5/19/23. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-205, filed 6/1/20, effective 7/1/20.]

WAC 246-945-210 Pharmacy technician—Temporary practice permit—Military spouse eligibility and issuance. A military spouse or state registered domestic partner of a member of the military may receive a temporary practice permit while completing any specific additional requirements that are not related to training or practice standards for a pharmacy technician certification. The commission adopts the procedural rules as adopted by the department of health in WAC 246-12-051.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-210, filed 6/1/20, effective 7/1/20.]

WAC 246-945-215 Pharmacy technician education and training programs. A pharmacy technician-training program must meet the minimum requirements of this section and be approved by the commission.

(1) A pharmacy technician-training program shall be considered approved by the commission if it is accredited, approved, or administered by:

(a) The American Society of Health-System Pharmacists (ASHP);

(b) The Accreditation Council for Pharmacy Education;

(c) Pharmacy Technician Certification Board; or

(d) The United States Armed Forces.

(2) A pharmacy technician education and training program not covered by subsection (1) of this section shall be considered meeting the requirements of RCW 18.64A.020 and approved by the commission if it meets the following minimum requirements:

(a) Prepare students for entry-level practice in a variety of settings including, but not limited to, community, hospital, and long-term care, this shall include:

(i) Orientation to pharmacy practice. Health care delivery systems, broad definitions of pharmacy practice and practice settings, communication techniques, confidentiality of information and safety considerations;

(ii) Basic pharmaceutics. Medical and pharmaceutical terminology and abbreviations, components of a prescription and patient medication record, drug dosage forms, routes of administration and drug product packaging, weighing and measuring, labeling, drug nomenclature, aseptic techniques, drug storage and handling, and drug standard and information sources;

(iii) Federal and state regulations. A minimum of eight hours in principles of applicable state and federal pharmacy laws, rules, regulations, guidelines, and interpretive statements; and

(iv) Pharmaceutical calculations. Basic mathematics including: Fractions, decimals, percentages, proportions, and weights and measures.

(b) Include a multicultural health curriculum as required by RCW 43.70.615.

(c) Have a pharmacist program director that is accountable for the overall quality of the program.

(d) Include minimum hours of education and training that extends over a period of fifteen weeks but under twenty-four months, and includes at a minimum:

(i) For vocational or technical training eight hundred hours which includes one hundred sixty hours supervised practice experience.

(ii) For formal or academic training programs two academic quarters with thirty credit hours each and includes one hundred sixty supervised practice experience.

(iii) On-the-job training of at least five hundred twenty hours with twelve hours of instructive education.

(3) To be approved by the commission a program must provide to the commission:

(a) A complete application;

(b) The name of a designated licensed pharmacist as program director;

(c) A list or copies of training manuals and reference;

(d) Content of instruction;

(e) Methods for evaluating trainees; and

(f) Verification of eight hours of pharmacy law study.

(4) Except for programs listed in subsection (1) of this section, a pharmacy technician-training program must renew every five years.

(5) Any substantive changes to the program or change in program director must be reported to the commission within thirty calendar days.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-215, filed 6/1/20, effective 7/1/20.]

WAC 246-945-217 Expired pharmacy technician certification. To return to active status a pharmacy technician with an expired certification shall pay the applicable fees in accordance with chapter 246-907 WAC, and:

(1) If a pharmacy technician's certification has expired for five years or less, the pharmacy technician shall meet the requirements of chapter 246-12 WAC, Part 2.

(2) If the pharmacy technician's certification has expired for over five years and they have not been in active practice in another U.S. jurisdiction, the pharmacy technician shall:

(a) Complete the requirements for certification under WAC 246-945-205; and

(b) Meet the requirements of chapter 246-12 WAC, Part 2.

(3) If the pharmacy technician's certification has expired for over five years and they have been in an active practice in another U.S. jurisdiction with duties that are substantially equivalent to a pharmacy technician in Washington state, the pharmacy technician shall:

(a) Submit verification of current active pharmacy practice in another U.S. jurisdiction; and

(b) Meet the requirements of chapter 246-12 WAC, Part 2.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-217, filed 6/1/20, effective 7/1/20.]

WAC 246-945-220 Pharmacy technician—Continuing education. (1) As part of the process to renew a pharmacy technician license, a pharmacy technician shall complete continuing pharmacy education (CPE) in compliance with this section.

(2) A pharmacy technician shall complete 2.0 CPE hours (equal to twenty contact hours) administered by an ACPE accredited program each certification renewal period.

(3) A pharmacy technician shall register with a program designated by the commission for tracking completed CPE hours.

(4) CPE hours cannot be carried over to the next renewal cycle.

[Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 21-04-145, § 246-945-220, filed 2/3/21, effective 12/1/21. Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-220, filed 6/1/20, effective 3/1/21.]

Subpart C – Pharmaceutical Firm Licensing

WAC 246-945-230 General information, change of location, ownership or new construction. (1) The definitions in this subsection apply throughout WAC 246-945-230 through 246-945-247 unless otherwise specified:

(a) "License" includes "licensing," "licensure," "certificate," "certification," and "registration."

(b) "Facility" includes pharmacies, nonresident pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers.

(2) The commission shall license a facility that:

(a) Submits a completed application for the license applied for on forms provided by the commission;

(b) Pays the applicable fees in accordance with chapter 246-907 WAC. This fee will not be prorated under any circumstances;

(c) Undergoes an inspection by the commission if the facility is located in Washington pursuant to WAC 246-945-005 that results in either no deficiencies or an approved plan of correction; and

(d) Obtains a controlled substances registration from the commission and is registered with the DEA if the facility intends to possess or distribute controlled substances.

(3) Once an initial license is issued, a licensed facility must:

(a) Notify the commission and pay a facility inspection fee in lieu of paying an original license fee for modifications or remodels. A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.

(b) Submit a new application on forms provided by the commission and pay the original license fee as established in chapter 246-907 WAC if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the original license fee in accordance with chapter 246-907 WAC whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation.

(i) Upon receipt of a change of ownership application and fees, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall delineate that violations during the pending application process shall be the sole responsibility of the seller.

(ii) This agreement shall be provided to the commission upon request.

(d) Notify the commission within thirty days of any changes to the information provided on their application.

(e) Notify the commission of any changes in their responsible pharmacy manager in accordance with WAC 246-945-480, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with chapter 246-907 WAC.

(4) A license is issued to a location and is not transferable.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-230, filed 6/1/20, effective 7/1/20.]

WAC 246-945-232 Pharmacy licensing. The commission shall issue a pharmacy license to an applicant that:

(1) Is in compliance with WAC 246-945-230;

(2) Has a designated responsible pharmacy manager; and

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-232, filed 6/1/20, effective 7/1/20.]

WAC 246-945-233 Hospital pharmacy associated clinics. (1) A parent hospital pharmacy may add or delete a hospital pharmacy associated clinic (HPAC) to a hospital pharmacy license at any time in compliance with WAC 246-945-230 (2)(a), (b), and (d).

(2) The HPAC must designate a responsible pharmacy manager and notify the commission of changes.

(3) HPAC locations are identified as follows:

(a) Category 1 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC and does not perform sterile or nonsterile compounding of drugs.

(b) Category 2 HPAC: Receives drugs transferred from the parent hospital pharmacy to the HPAC and performs sterile or nonsterile compounding of drugs.

(4) A HPAC licensed under the parent hospital pharmacy license must obtain a separate DEA registration in order to possess controlled substances.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-233, filed 6/1/20, effective 7/1/20.]

WAC 246-945-235 Nonresident pharmacy license. The commission shall issue a nonresident pharmacy license to an applicant that:

(1) Provides all information required by RCW 18.64.360;

(2) Is in compliance with WAC 246-945-230;

(3) Has identified a responsible pharmacy manager, whose license is in good standing in the U.S. jurisdiction in which they are located; and

(4) Has provided to the commission proof that its resident license is in good standing.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-235, filed 6/1/20, effective 7/1/20.]

WAC 246-945-245 Health care entity license. (1) The commission shall issue a health care entity license to an applicant that:

(a) Is in compliance with WAC 246-945-230; and

(b) Has designated a responsible pharmacy manager.

(2) An organization (e.g., a clinic) must obtain a separate license for each of its locations. One organization occupying multiple suites in one facility is deemed to be occupying one location requiring one license. Separate organizations occupying the same location must obtain separate licenses.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-245, filed 6/1/20, effective 7/1/20.]

WAC 246-945-246 Wholesaler. (1) Every wholesaler who engages in wholesale distribution into, out of, or within Washington state must be licensed by the commission before engaging in wholesale distribution of drugs. Entities required to be licensed as a wholesaler includes:

(a) In-state and out-of-state pharmaceutical wholesalers;

(b) Out-of-state manufacturer that distribute or sell drugs into Washington;

(c) Virtual wholesalers;

(d) Out-of-state virtual manufacturers that distribute or sell drugs into Washington;

(e) Outsourcing facilities required to be registered with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) that are located in Washington, or distribute or sell drugs into Washington; and

(f) Reverse distributors.

(2) The commission may issue a wholesaler license to an applicant that is in compliance with the requirements in WAC 246-945-230 and this section.

(3) In addition to the requirements in subsection (2) of this section if the applicant is located outside of Washington, the applicant must provide:

(a) A copy of a site inspection conducted by the regulatory authority in the resident U.S. jurisdiction or third-party inspection program recognized by the commission within the last two years and every two years with the distributor's renewal;

(b) A copy of the resident state license; and

(c) A list of licenses, registrations, permits or certificates held in other U.S. jurisdictions.

(4) In addition to the requirements in subsection (2) of this section if the applicant plans to export noncontrolled drugs to persons in a foreign jurisdiction, the applicant must provide letters from the consulate of the country to which the drugs are exported and should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the commission upon its request. The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.

(5) Minimum qualifications. The commission shall consider, at a minimum, the following factors in reviewing the qualifications of in-

dividuals who engage in wholesale distribution of prescription drugs within the state:

(a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;

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

(c) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(d) Any false or fraudulent material furnished by the applicant on any application made in connection with drug manufacturing or distribution;

(e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) Compliance with licensing requirements under any previously granted licenses;

(g) Compliance with requirements to maintain and make available to the commission, federal, state, or local enforcement officials those records required to be maintained by wholesale drug distributors; and

(h) Any other factors or qualifications the commission considers relevant to and consistent with public health and safety.

(6) When operations are conducted at more than one location by a single wholesale distributor, each location shall be licensed by the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-246, filed 6/1/20, effective 7/1/20.]

WAC 246-945-247 Pharmaceutical manufacturer license. (1) An entity located in Washington state that manufactures drugs must be licensed by the commission in accordance with the laws and regulations of Washington state before engaging in manufacturing.

(2) The commission shall issue a manufacturer license to an applicant that is in compliance with the requirements in WAC 246-945-230.

(3) When operations are conducted at more than one location by a single manufacturer, each location shall be licensed by the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-247, filed 6/1/20, effective 7/1/20.]

Subpart D – Commission Registrations

WAC 246-945-250 Researcher and other controlled substance registration. (1) Applicants for initial registration and renewal for researcher or other controlled substance registrations shall submit to the commission a complete application with fees relevant to the registration type.

(a) Researcher:

(i) Noncontrolled legend drugs; or

(ii) Researchers requiring to purchase, possess, administer or dispense controlled substances shall apply for a controlled substance authority on its license with the commission and register with the DEA.

(b) Other controlled substance registrations:

(i) Opioid treatment programs;

(ii) Analytical laboratories;

(iii) Dog handler; and

(iv) Other agencies who have demonstrated a legitimate need to use precursor chemicals.

(2) The application shall:

(a) List all legend drugs and controlled substances to be used and the purpose for its use;

(b) Name the primary registrant; and

(c) List the names of the individuals authorized to access the controlled substances.

(3) Applicants shall undergo an initial inspection and periodic inspections as deemed appropriate by the commission.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-250, filed 6/1/20, effective 7/1/20.]

WAC 246-945-253 Shopkeeper registration. (1) A shopkeeper registration is issued to a business license authorizing the holder to purchase, possess, and sell over-the-counter medications as defined in RCW 18.64.044 and chapter 69.43 RCW, if applicable.

(2) A business entity with a licensed pharmacy with different operating hours shall hold a shopkeeper registration to acquire, possess, and sell over-the-counter medications when the pharmacy is closed.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-253, filed 6/1/20, effective 7/1/20.]

WAC 246-945-254 Animal control and humane society registration. (1) Humane societies and animal control agencies registered with the commission under RCW 69.50.310 may purchase, possess, and administer sodium pentobarbital and approved legend drugs as provided in RCW 69.41.080.

(2) To apply for registration, a humane society or animal control agency shall submit to the commission a completed application for reg-

istration on forms provided by the commission and undergo an initial inspection.

(3) The registered agency shall designate an individual responsible for maintaining all records and submitting all reports required by applicable federal or state law or rule.

(4) The registered agency shall provide to the commission a list of staff trained and authorized to administer approved drugs.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-254, filed 6/1/20, effective 7/1/20.]

WAC 246-945-255 Chemical capture—Department of fish and wildlife. (1) The department of fish and wildlife may apply to the commission for a limited registration under chapters 69.50 and 69.41 RCW to purchase, possess, and administer controlled substances and legend drugs for use in chemical capture programs.

(2) Each department of fish and wildlife field office that stores controlled substances or legend drugs must register with the commission. The department of fish and wildlife must notify the commission of the names of individuals who are authorized to possess and administer controlled substances and legend drugs.

(3) The department of fish and wildlife shall designate one individual at each field office who shall be responsible for the ordering, possession, safe storage, and utilization of controlled substances and legend drugs. The department of fish and wildlife shall notify the commission of the name of the designated individual.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-255, filed 6/1/20, effective 7/1/20.]

PART 3 - PROFESSIONAL STANDARDS

WAC 246-945-305 Pharmacist's professional responsibilities. (1) A pharmacist shall be knowledgeable of, and comply with, all applicable rules and laws.

(2) A pharmacist is responsible for providing patients with safe and appropriate medication therapy.

(3) A pharmacist shall be responsible for any delegated act performed by pharmacy interns, pharmacy technicians, and pharmacy assistants under their supervision.

(4) A pharmacist shall delegate pharmacy functions in accordance with WAC 246-945-315.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253,

18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-305, filed 6/1/20, effective 7/1/20.]

WAC 246-945-310 Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-310, filed 6/1/20, effective 7/1/20.]

WAC 246-945-315 Delegation of pharmacy functions to pharmacy ancillary personnel. (1) All delegated pharmacy functions shall be performed under a pharmacist's immediate supervision. A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(2) When delegating a pharmacy function to a pharmacy technician:

(a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and

(b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320.

(3) A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following:

(a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and

(b) Count, pour, and label for individual prescriptions.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-315, filed 6/1/20, effective 7/1/20.]

WAC 246-945-317 Tech check tech. (1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of

the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example.

(2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-317, filed 6/1/20, effective 7/1/20.]

WAC 246-945-320 Nondelegable tasks. (1) A pharmacist shall not delegate the following to ancillary personnel:

(a) Receipt or transfer of a verbal prescription other than refill authorization from a prescriber.

(b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling regarding any information contained in a patient medication record system; however, this shall not prohibit pharmacy ancillary personnel from providing to or receiving from the patient or the patient's agent certain information where no professional judgment is required.

(c) Consultation with the prescriber regarding the patient and the patient's prescription.

(d) Interpretation of data in a patient medication record system.

(e) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.

(f) Patient counseling in accordance with WAC 246-945-325.

(g) Substitution of a biological or drug product in accordance with WAC 246-945-340.

(h) Decision to not dispense lawfully prescribed drugs or devices or to not distribute drugs and devices approved by the FDA for restricted distribution by pharmacies.

(i) Prescription adaptation in accordance with WAC 246-945-335.

(2) A pharmacy intern can perform any pharmacy function based on their education, skill and experience, except supervising other pharmacy personnel.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-320, filed 6/1/20, effective 7/1/20.]

WAC 246-945-325 Patient counseling. (1) The pharmacist shall offer to counsel:

(a) Upon the initial fill of a prescription for a new or change of therapy.

(b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient.

(2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-325, filed 6/1/20, effective 7/1/20.]

WAC 246-945-330 Refilling prescriptions. (1) A prescription may be refilled when permitted by state and federal law and only as authorized by the prescriber.

(2) Except as provided in subsection (1) of this section, a pharmacist may renew a prescription for a noncontrolled legend drug one time in a six-month period when an effort has been made to contact the prescriber and they are not available for authorization under the following conditions:

(a) The amount dispensed is the quantity on the most recent fill or a thirty-day supply, whichever is less;

(b) The refill is requested by the patient or the patients agent;

(c) The patient has a chronic medical condition;

(d) No changes have been made to the prescription; and

(e) The pharmacist communicates the renewal to the prescriber within one business day.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-330, filed 6/1/20, effective 7/1/20.]

WAC 246-945-332 Continuity of care. When the governor issues an emergency proclamation for an event which prevents continuity of health care for persons and animals because their prescribed medications are no longer available to them due to the emergency event, pharmacists and pharmacies may provide emergency prescription supplies for medications during the period of the proclaimed emergency as provided below:

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

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

(b) If the prescription is expired or has no refills and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of the last dispensed quantity or up to a thirty-day supply of a maintenance medication.

(c) If the patient is unable to provide either a valid prescription or prescription container the pharmacist may use their professional judgment when accepting a provider reconciled medication list.

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

(a) Document the dispensing as a prescription, noting where the information from subsection (1)(a) of this section was obtained;

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

(c) Record the prescription or patient record as an "emergency" prescription.

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-332, filed 6/1/20, effective 7/1/20.]

WAC 246-945-335 Prescription adaptation. Upon patient consent, a pharmacist may adapt drugs as specified in this rule, provided that the prescriber has not indicated that adaptation is not permitted.

(1) Change quantity. A pharmacist may change the quantity of medication prescribed if:

(a) The prescribed quantity or package size is not commercially available;

(b) The change in quantity is related to a change in dosage form;

(c) The change is intended to dispense up to the total amount authorized by the prescriber including refills in accordance with RCW 18.64.520; or

(d) The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program in accordance with RCW 48.43.096.

(2) Change dosage form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed.

(3) Complete missing information. A pharmacist may complete missing information on a prescription if there is evidence to support the change.

(4) Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-335, filed 6/1/20, effective 7/1/20.]

WAC 246-945-340 Prescriptions—Drug product substitutions. (1) A pharmacist may substitute a drug or biologic product dispensed pursuant to a prescription if in compliance with applicable laws and rules.

(2) A pharmacist may substitute a drug product or a biologic product when any of the following applies:

(a) The substitution is permitted by RCW 69.41.120;

(b) The substitution is permitted by a formulary developed by an interdisciplinary team of an institutional facility; or

(c) The substitution is otherwise permitted by law.

(3) In addition to any other applicable requirements, a pharmacist shall only substitute a drug or a biologic product pursuant to subsection (2)(b) of this section if:

(a) An employee or contractor of the institutional facility prescribed the drug or biologic product to be substituted;

(b) The interdisciplinary team was composed of a nonpharmacist prescriber listed in RCW 69.41.030 and a pharmacist; and

(c) The formulary is readily retrievable by the pharmacist.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-340, filed 6/1/20, effective 7/1/20.]

WAC 246-945-345 Prescription transfers. (1) Subsections (2) through (5) of this section apply to the transfer of prescription information for noncontrolled drugs. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec. 1306.25.

(2) Upon patient request, a prescription may be transferred within the limits of state and federal law.

(3) Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription.

(4) Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing.

(5) Prescriptions must be transferred by electronic means or facsimile, except in emergent situations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-345, filed 6/1/20, effective 7/1/20.]

WAC 246-945-350 Collaborative drug therapy agreements. (1) A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location.

(2) A CDTA must include:

(a) A statement identifying the practitioner authorized to prescribe and the name of each pharmacist who is party to the agreement;

(i) The practitioner authorized to prescribe must be in active practice; and

(ii) The authority granted must be within the scope of the practitioners' current practice.

(b) A statement of the type of prescriptive authority decisions which the pharmacist is authorized to make, which includes:

(i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case.

(ii) A general statement of the training required, procedures, decision criteria, or plan the pharmacist is to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved.

(c) A statement of the activities the pharmacist is to follow in the course of exercising prescriptive authority, including:

(i) Documentation of decisions made; and

(ii) A plan for communication or feedback to the authorizing practitioner concerning specific decisions made.

(3) A CDTA is only valid for two years from the date of signing.

(4) Any modification of the written guideline or protocol shall be treated as a new CDTA.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-350, filed 6/1/20, effective 7/1/20.]

WAC 246-945-355 Monitoring of drug therapy by pharmacist. In the absence of a CDTA, the term "monitoring drug therapy" used in RCW 18.64.011 shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering or reviewing laboratory tests, imaging, and social evaluation related to an existing diagnosis and drug therapies for optimization of drug therapy.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-355, filed 6/1/20, effective 7/1/20.]

WAC 246-945-360 Patient rights. Any person authorized to practice or assist in the practice of pharmacy shall not engage in any of the following:

(1) Destroy unfilled lawful prescription;

(2) Refuse to return unfilled lawful prescriptions;

(3) Violate a patient's privacy;

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

(5) Intimidate or harass a patient.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-360, filed 6/1/20, effective 7/1/20.]

WAC 246-945-365 Approval of impaired practitioner substance abuse monitoring program. (1) The commission will approve recovery, assistance and monitoring programs under RCW 18.130.175 for its credential holders.

(2) For the purposes of RCW 18.130.175(1), the commission will consider a licensee to have not successfully completed the program if they are discharged from the program for failure to comply with the program's terms and conditions.

(3) A licensee referred or required to participate in a program will be subject to disciplinary action under chapter 18.130 RCW if they fail to sign or otherwise revoke a waiver allowing the program to release information to the commission.

(4) An approved program shall report a licensee who fails to comply with the program's terms and conditions within seven calendar days.

(5) A licensee shall report themselves to the commission if they fail to comply with RCW 18.130.175, the program's terms and conditions, or any part of this section within seven calendar days. The fact an approved program has reported under subsection (4) of this section does not absolve the licensee of a responsibility to report.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-365, filed 6/1/20, effective 7/1/20.]

WAC 246-945-370 Sexual misconduct. (1) A pharmacy health care practitioner must not engage, or attempt to engage, in sexual misconduct with a current patient, client, or key party, inside or outside the health care setting. Sexual misconduct shall constitute grounds for disciplinary action.

(2) Practitioner under this section shall be defined as any person credentialed under RCW 18.64.080 or chapter 18.64A RCW.

(3) Sexual misconduct includes, but is not limited to:

(a) Sexual intercourse;

(b) Touching the breasts, genitals, anus or any sexualized body part except as consistent with accepted community standards of practice within the health care practitioner's scope of practice;

(c) Rubbing against a patient, client, or key party for sexual gratification;

(d) Kissing;

(e) Hugging, touching, fondling or caressing of a romantic or sexual nature;

(f) Not allowing a patient or client privacy to dress or undress except as may be necessary in emergencies or custodial situations;

(g) Not providing the patient or client a gown or draping except as may be necessary in emergencies;

(h) Dressing or undressing in the presence of the patient, client, or key party;

(i) Removing patient's or client's clothing or gown or draping without consent, except emergent medical necessity or being in a custodial setting;

(j) Encouraging masturbation or other sex act in the presence of the health care provider;

(k) Masturbation or other sex act by the health care provider in the presence of the patient, client, or key party;

(l) Suggesting or discussing the possibility of a dating, sexual or romantic relationship after the professional relationship ends;

(m) Terminating a professional relationship for the purpose of dating or pursuing a romantic or sexual relationship;

(n) Soliciting a date with a patient, client, or key party;

(o) Discussing the sexual history, preferences or fantasies of the health care provider;

(p) Any behavior, gestures, or expressions that may reasonably be interpreted as seductive or sexual;

(q) Making statements regarding the patient, client, or key party's body, appearance, sexual history, or sexual orientation other than for legitimate health care purposes;

(r) Sexually demeaning behavior including any verbal or physical contact which may reasonably be interpreted as demeaning, humiliating, embarrassing, threatening or harming a patient, client, or key party;

(s) Photographing or filming the body or any body part or pose of a patient, client, or key party, other than for legitimate health care purposes; and

(t) Showing a patient, client, or key party sexually explicit materials, other than for legitimate health care purposes.

(4) Sexual misconduct also includes sexual contact with any person involving force, intimidation, or lack of consent; or a conviction of a sex offense as defined in RCW 9.94A.030.

(5) A health care practitioner must not:

(a) Offer to provide health care services in exchange for sexual favors;

(b) Use health care information to contact the patient, client, or key party for the purpose of engaging in sexual misconduct;

(c) Use health care information or access to health care information to meet or attempt to meet the health care practitioner's sexual needs.

(6) A health care practitioner must not engage, or attempt to engage, in the activities listed in subsection (4) of this section with a former patient, client, or key party if:

(a) There is a significant likelihood that the patient, client, or key party will seek or require additional services from the health care practitioner; or

(b) There is an imbalance of power, influence, opportunity, or special knowledge of the professional relationship.

(7) When evaluating whether a health care provider engaged, or attempted to engage, in sexual misconduct, the commission will consider factors including, but not limited to:

(a) Documentation of a formal termination and the circumstances of termination of the practitioner-patient relationship;

(b) Transfer of care to another health care practitioner;

(c) Duration of the practitioner-patient relationship;

(d) Amount of time that has passed since the last health care services to the patient or client;

(e) Communication between the health care practitioner and the patient or client between the last health care services rendered and commencement of the personal relationship;

(f) Extent to which the patient's or client's personal or private information was shared with the health care practitioner;

(g) Nature of the patient or client's health condition during and since the professional relationship;

(h) The patient or client's emotional dependence and vulnerability; and

(i) Normal revisit cycle for the profession and service.

(8) Patient, client, or key party initiation or consent does not excuse or negate the health care practitioner's responsibility.

(9) These rules do not prohibit:

(a) Providing health care services in case of emergency where the services cannot or will not be provided by another health care provider;

(b) Contact that is necessary for a legitimate health care purpose and that meets the standard of care appropriate to that profession; or

(c) Providing health care services for a legitimate health care purpose to a person who is in a preexisting, established personal relationship with the health care provider where there is no evidence of, or potential for, exploiting the patient or client.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-370, filed 6/1/20, effective 7/1/20.]

PART 4 – OPERATIONAL STANDARDS

Subpart A – Pharmacies, HCEs and HPACs

WAC 246-945-405 Applicability. (1) The rules in this chapter apply to pharmacies, health care entities (HCE), and hospital pharmacy associated clinics (HPAC).

(2) Unless specified, the term "facility" as used in this part includes pharmacies, HCEs, and HPACs.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-405, filed 6/1/20, effective 7/1/20.]

WAC 246-945-410 Facility standards. A facility must meet the following minimum requirements:

(1) The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices,

and other restricted sale items from unauthorized access, acquisition, or use.

(2) The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.

(3) The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation.

(4) The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415.

(5) The facility shall designate a responsible pharmacy manager:

(a) By the date of opening; and

(b) Within thirty calendar days of a vacancy.

(6) The facility shall create and implement policies and procedures related to:

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

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

(c) Adequate security of legend drugs, including controlled substances.

(d) Controlling access to legend drugs, including controlled substances.

(7) Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011.

(8) A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if:

(a) The drug is a subsequent dose from a previously reviewed prescription;

(b) The prescriber is in the immediate vicinity and controls the drug dispensing process;

(c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or

(d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening.

(9) Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325.

(10) Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies:

(a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or

(b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or

(c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice.

(11) In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants:

(a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320.

(b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3).

(12) A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows:

(a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions.

(b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-410, filed 6/1/20, effective 7/1/20.]

WAC 246-945-415 Dispensing and delivery of prescription drugs. (1) A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.

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

(a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-945-410(8) or 246-945-335;

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

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

(d) Potentially fraudulent prescriptions; or

(e) Unavailability of drug or device despite good faith compliance with WAC 246-945-410(4).

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

(4) If despite good faith compliance with WAC 246-945-410(4), the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (2)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include, but are not limited to:

(a) Contact the prescriber to address concerns such as those identified in subsection (2)(a) of this section or to obtain authorization to provide a therapeutically equivalent product;

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

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

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

(a) Destroy unfilled lawful prescriptions;

(b) Refuse to return unfilled lawful prescriptions;

(c) Violate a patient's privacy;

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

(e) Intimidate or harass a patient.

(6) Filled prescriptions may be picked up or returned for delivery by authorized personnel when the pharmacy is closed for business if the prescriptions are placed in a secured delivery area outside of the drug storage area. The secured delivery area must be a part of a licensed pharmacy, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft, or diversion. Access to the secured delivery area must be addressed by the policies and procedures developed by the responsible pharmacy manager.

(7) HCEs shall dispense in accordance with RCW 18.64.450.

(8) A licensed hospital pharmacy dispensing appropriately labeled, patient specific drugs to a HPAC licensed under the parent hospital pharmacy may do so only pursuant to a valid prescription and prescription information is authenticated in the medical record of the patient to whom the legend drug or controlled substance will be provided according to the policy and procedures of the parent hospital pharmacy.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-415, filed 6/1/20, effective 7/1/20.]

WAC 246-945-417 Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records. (1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill,

transfer information, and other information necessary to provide safe and appropriate patient care.

(a) Systems must prevent auto-population of user identification information.

(b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services.

(2) The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible.

(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:

(a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and

(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.

(4) The pharmacy shall have policies and procedures in place for system downtime.

(a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter.

(b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed.

(c) This section does not require that a permanent dual recordkeeping system be maintained.

(5) The pharmacy shall maintain records in accordance with WAC 246-945-020.

(6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311.

(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-417, filed 6/1/20, effective 7/1/20.]

WAC 246-945-418 Paper recordkeeping procedure. If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310,

18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-418, filed 6/1/20, effective 7/1/20.]

WAC 246-945-420 Facility inventory requirements. (1) A facility shall conduct its own separate inventory of prescription drugs when it closes in accordance WAC 246-945-480.

(2) A facility shall conduct an inventory of controlled substances every two years.

(3) A facility shall conduct its own separate inventory of controlled substances in the following situations:

(a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory.

(b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory.

(4) A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory.

(5) A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-420, filed 6/1/20, effective 7/1/20.]

WAC 246-945-425 Shared pharmacy services. Pharmacy services may be provided off-site at one or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following:

(1) Long term care shared pharmacy services in accordance with RCW 18.64.570.

(2) Central fill shared pharmacy services in accordance with the following conditions:

(a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party;

(b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform off-site pharmacy services; and

(c) A single prescription may be shared by an originating pharmacy and a central fill pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-425, filed 6/1/20, effective 7/1/20.]

WAC 246-945-430 Pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site. (1) The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies.

(2) The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high quality recording for a minimum of thirty calendar days.

(3) Access to a pharmacy by individuals must be limited, authorized, and regularly monitored.

(4) A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant.

(5) The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy.

(6) A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises.

(7) The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-430, filed 6/1/20, effective 7/1/20.]

WAC 246-945-435 Provision of emergency department discharge medication when pharmacy services are unavailable. (1) The responsible pharmacy manager of a hospital or free standing emergency department may, in collaboration with the appropriate medical staff committee of the hospital, develop policies and procedures to provide discharge medications to patients released from hospital emergency departments during hours when community or outpatient hospital pharmacy services are not available.

(2) The policies and procedures in subsection (1) of this section shall:

(a) Comply with all requirements of RCW 70.41.480;

(b) Ensure all prepackaged medications are affixed with a label that complies with WAC 246-945-018;

(c) Require oral or electronically transmitted chart orders be verified by the practitioner in writing within seventy-two hours;

(d) The medications distributed as discharge medications are stored in compliance with the laws concerning security and access; and

(e) Ensure discharge medications are labeled appropriately.

(3) The delivery of a single dose for immediate administration to the patient is not subject to this regulation.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-435, filed 6/1/20, effective 7/1/20.]

WAC 246-945-440 Administration of patient owned medications. Facilities shall develop written policies and procedures for the administration of patient owned medications.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-440, filed 6/1/20, effective 7/1/20.]

WAC 246-945-445 Investigational drugs. (1) The responsible pharmacy manager or their designee is responsible for the storage, distribution, and control of approved investigational drugs used in an institutional facility. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.

(2) Under the explicit direction of the authorized principal investigator, coinvestigator(s), or per study protocol requirements, investigational drugs must be properly labeled and stored for use. An appropriate medical staff committee, institution review board, or equivalent committee, shall approve the use of such drugs.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-445, filed 6/1/20, effective 7/1/20.]

WAC 246-945-450 Accessing technology used to dispense—Nursing students. (1) Nursing students may be given access privileges to technology used to dispense medications for patient administration as provided for in this section.

(2) Nursing students must be enrolled in a nursing program approved by the Washington state nursing care quality assurance commission in accordance with WAC 246-840-510.

(3) A facility that provides a clinical opportunity to nursing students must meet the following to grant access to technology used to dispense medications for patient administration:

(a) The facility, in collaboration with the nursing program, shall provide nursing students with orientation and practice experiences that include the demonstration of competency of skills prior to using the dispensing technology;

(b) Nursing programs and participating facilities shall provide adequate training for students accessing dispensing technology;

(c) The nursing programs and participating facilities shall have policies and procedures for nursing students to provide safe administration of medications; and

(d) The nursing program and participating facilities shall develop and have a way of reporting and resolving any nursing student medication errors, adverse events, and alleged diversion.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-450, filed 6/1/20, effective 7/1/20.]

WAC 246-945-455 Drugs stored outside of the pharmacy. (1) In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met:

(a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy;

(b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures;

(c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450;

(d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and

(e) The facility is able to possess and store drugs.

(2) For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-455, filed 6/1/20, effective 7/1/20.]

WAC 246-945-460 Staffing and supervision of pharmacy staff. (1) The ratio of pharmacy technicians to pharmacist(s) on duty is to be determined by the responsible pharmacy manager.

(2) The responsible pharmacy manager will ensure that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist(s) on duty.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-460, filed 6/1/20, effective 7/1/20.]

WAC 246-945-480 Facility reporting requirements. (1) The outgoing and incoming responsible pharmacy manager must report in writing

to the commission a change in a responsible manager designation within ten business days of the change.

(2) Unless otherwise specified, when permanently closing a facility, the facility must:

(a) Report to the commission in writing, no later than thirty calendar days prior to closing:

(i) The date the facility will close;

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

(iii) The names and addresses of any person(s) who will acquire any legend drugs from the facility to be closed, if known at the time the notification is filed.

(b) Provide notification to customers noting the last day the pharmacy will be open, name and address of the pharmacy to which prescription records will be transferred and instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice and the last day a transfer may be initiated. Notification should include:

(i) Distribution by direct mail; or

(ii) Public notice in a newspaper of general circulation in the area served by the pharmacy; and

(iii) Posting a closing notice sign in a conspicuous place in the public area of the pharmacy.

(c) No later than fifteen days after closing:

(i) Return the facility license;

(ii) Confirm that all legend drugs were transferred or destroyed. If the legend drugs were transferred, provide the names and addresses of the person(s) to whom they were transferred;

(iii) Confirm if controlled substances were transferred, including the date of transfer, names, addresses, and a detailed inventory of the drugs transferred;

(iv) Confirm return of DEA registration and all unused DEA 222 forms to the DEA;

(v) Confirm all pharmacy labels and blank prescriptions were destroyed; and

(vi) Confirm all signs and symbols indicating the presence of the pharmacy have been removed.

(3) The commission may conduct an inspection to verify all requirements in subsection (2) of this section have been completed.

(4) The facility shall immediately report to the commission any 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.

(5) Any facility credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-480, filed 6/1/20, effective 7/1/20.]

WAC 246-945-485 Destruction or return of drugs or devices—Restrictions. (1) A dispensed drug or prescription device must only be accepted for return and reuse as follows:

(a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured.

(b) Those that qualify for return under the provisions of chapter 69.70 RCW.

(2) A dispensed drug or prescription device may be accepted for return and destruction if:

(a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions;

(b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or

(c) The return and destruction is in compliance with the facility's policies and procedures.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-485, filed 6/1/20, effective 7/1/20.]

WAC 246-945-486 Return and reuse of unexpired medications—Department of corrections. (1) For the purposes of this section, the term "facilities" includes all facilities served by the Washington state department of corrections pharmacy.

(2) The Washington state department of corrections pharmacy may accept for return and reuse noncontrolled legend drugs in unit dose packages, or full or partial multiple dose medication cards from the facilities it serves, if product integrity can be assured and the Washington state department of corrections pharmacy complies with RCW 69.70.050 (1), (2), and (5).

[Statutory Authority: RCW 18.64.005 and 2020 c 264. WSR 23-11-088, § 246-945-486, filed 5/17/23, effective 6/17/23.]

WAC 246-945-488 Safe donation of unexpired prescription drugs. (1) For the purposes of this section, the definitions in RCW 69.70.010 apply.

(2) A pharmacy that accepts, distributes, or dispenses prescription drugs and supplies under WAC 246-945-485 (1)(b) that are donated shall:

(a) Comply with the requirements in RCW 69.70.020, 69.70.030, 69.70.040, and 69.70.050, when applicable;

(b) Complete and return an attestation form developed and supplied by the commission attesting to participation in the drug donation program;

(c) Notify the commission in writing if it is no longer accepting donated prescription drugs and supplies. This notification must occur within thirty calendar days of the pharmacy no longer accepting donated prescription drugs and supplies;

(d) Not accept donations of prescription drugs and supplies via a drop box;

(e) Ensure that prescription drugs and supplies donated by the person to whom the prescription drug was prescribed or the person's representative are accompanied by the department's drug donation form in accordance with RCW 69.70.020(2);

(f) Ensure clear separation of the pharmacy's donated prescription drug stock from the rest of the pharmacy's drug stock;

(g) Maintain a separate inventory of all prescription drugs and supplies donated to the pharmacy; and

(h) Develop and implement policies and procedures addressing:

(i) When prescription drugs or supplies may be accepted and dispensed. The policy and procedure shall require a pharmacist to inspect the donated prescription drugs and supplies; and

(ii) How the pharmacy will respond when it is informed of a recall for donated prescription drugs and supplies.

(3) Practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, persons to whom a prescription drug was prescribed, or the person's representative, are not required to obtain a wholesaler license when donating prescription drugs to a pharmacy.

[Statutory Authority: RCW 18.64.005 and 2020 c 264. WSR 23-11-088, § 246-945-488, filed 5/17/23, effective 6/17/23.]

WAC 246-945-490 Nuclear pharmacies. (1) The commission shall issue a permit to operate a nuclear pharmacy providing radiopharmaceutical services to a qualified nuclear pharmacist. The qualified nuclear pharmacist shall:

(a) Supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals.

(b) Be responsible for all operations of the licensed area.

(c) Designate one or more qualified health care professionals licensed under the chapters specified in RCW 18.130.040, to have access to the licensed area in emergency situations and in the nuclear pharmacist's absence. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) A nuclear pharmacy shall have adequate space that is appropriate with the scope of services provided, including meeting the following requirements:

(a) The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel;

(b) A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the commission; and

(c) Detailed floor plans shall be submitted to the commission and the state radiation control agency before approval of the pharmacy license.

(3) A nuclear pharmacy shall prepare, compound, and dispense radiopharmaceuticals in accordance with USP <825>.

(4) The preparation of nuclear pharmaceuticals requires the compounding skills of the nuclear pharmacist and shall be done to assure that the final drug product meets USP <825>.

(5) A nuclear pharmacy shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable

regulations of the commission, the state radiation control agency and other state and federal agencies.

(6) For a nuclear pharmacy handling radiopharmaceuticals exclusively, the commission may waive regulations pertaining to the pharmacy permits for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(7) 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. In absence of a prescription for an individual identified patient, the statement "Office Use Only" should be applied.

(8) 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.

(9) In addition to labeling requirements of WAC 246-945-015 through 246-945-017 for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with:

(a) Standard radiation symbol;

(b) The words "caution-radioactive material";

(c) Radionuclide and chemical form (generic name);

(d) Activity dispensed with units (millicuries or microcuries) at calibration date and time;

(e) If a liquid, the volume in milliliters;

(f) Calibration date and time for the dose;

(g) BUD and special storage and handling instructions for nonimmediate use;

(h) Specific concentration of radioactivity; and

(i) The patient name/identifier, and number of dosage units dispensed, for all therapeutic and blood-products.

(10) The immediate container of the radiopharmaceutical to be dispensed shall be labeled with:

(a) The standard radiation symbol;

(b) The words "caution-radioactive material";

(c) The name of the nuclear pharmacy;

(d) The prescription number;

(e) Radionuclide and chemical form (generic name)";

(f) The date;

(g) Activity dispensed with units (millicuries or microcuries) at calibration date and time; and

(h) The patient name/identifier for all therapeutic and blood-products.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) A nuclear pharmacy may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have readily available the current applicable state laws and regulations of the commission and state radiation control agency.

(14) The nuclear pharmacy shall maintain, and submit to the commission and state radiation control agency, a library commensurate with the level of radiopharmaceutical service to be provided before approval of the license.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-490, filed 6/1/20, effective 7/1/20.]

WAC 246-945-492 Nuclear pharmacies—Equipment requirements. (1) A nuclear pharmacy shall have adequate equipment appropriate with the scope of radiopharmaceutical services to be provided. The nuclear pharmacy shall submit to the commission and the radiation control agency a detailed list of equipment and description of use before approval of the license.

(2) The commission may, for good cause shown, waive regulations pertaining to the equipment and supplies required for a nuclear pharmacy handling radiopharmaceuticals exclusively.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-492, filed 6/1/20, effective 7/1/20.]

Subpart B – Registrations

WAC 246-945-500 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Designated person. (1) Each registered humane society, animal control agency, and department of fish and wildlife chemical capture program location shall have a designated person.

(2) The designated person is responsible for:

(a) Ordering, possession, safe storage and use of all approved drugs;

(b) Maintaining all records required by WAC 246-945-510; and

(c) Ensuring all records required by WAC 246-945-510 are available for inspection by the commission or its designee.

(3) A registered humane society, animal control agency, or department of fish and wildlife chemical capture program shall notify the commission within ten calendar days of a change in the designated person.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-500, filed 6/1/20, effective 7/1/20.]

WAC 246-945-503 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Authorized personnel. (1) Each registered humane society, animal control agency, and department of fish and wildlife chemical capture program location shall ensure only authorized personnel possess or administer approved

legend drugs and approved controlled substances at the registered location.

(2) For registered humane societies and animal control agencies, authorized personnel are those individuals who have:

(a) Completed a commission-approved training program or training that is substantially equivalent; and

(b) Been approved by the designated person.

(3) For registered department of fish and wildlife chemical capture programs, authorized personnel are those individuals who have:

(a) Completed a commission-approved training program or training that is substantially equivalent;

(b) Been approved by the department of fish and wildlife; and

(c) Are a department of fish and wildlife officer, biologist, or veterinarian.

(4) A commission-approved training program shall include didactic and practical training under the direction of a licensed veterinarian. The commission-approved training program should ensure that authorized personnel shall be able to demonstrate adequate knowledge of the potential hazards and proper techniques used in administering approved legend and controlled substances.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-503, filed 6/1/20, effective 7/1/20.]

WAC 246-945-505 Humane societies and animal control agencies—Approved legend drugs and approved controlled substances. (1) The following legend drugs are designated as "approved legend drugs" for use by registered humane societies and animal control agencies for pre-euthanasia sedation:

(a) Acetylpromazine;

(b) Dexmedetomidine;

(c) Medetomidine; and

(d) Xylazine.

(2) Registered humane societies and animal control agencies may only use sodium pentobarbital to euthanize injured, sick, homeless or unwanted domestic pets, and domestic or wild animals.

(3) Any approved drug used by the registered humane society and animal control agency shall be marked "for veterinary use only."

(4) Staff of registered humane societies and animal control agencies may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal, which have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either RCW 18.64.246 or 69.41.050 and WAC 246-945-015 through 246-945-017.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-505, filed 6/1/20, effective 7/1/20.]

WAC 246-945-507 Department of fish and wildlife chemical capture programs—Approved legend drugs and approved controlled substances. (1) The following legend drugs are designated as "approved legend drugs" for use by registered department of fish and wildlife chemical capture programs:

(a) Acetylpromazine;
(b) Atipamezole;
(c) Azaperone;
(d) Detomidine;
(e) Dexmedetomidine;
(f) Isoflurane;
(g) Medetomidine;
(h) Naltrexone;
(i) Tolazoline;
(j) Xylazine; and
(k) Yohimbine.

(2) The following controlled substances are controlled substances approved for use by registered department of fish and wildlife chemical capture programs:

(a) Butorphanol;
(b) Diazepam;
(c) Diprenorphine;
(d) Carfentanil;
(e) Fentanyl;
(f) Ketamine;
(g) Midazolam;
(h) Tiletamine; and
(i) Zolazepam.

(3) Staff of registered department of fish and wildlife chemical capture programs may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal or management group of animals, which have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either RCW 18.64.246 or 69.41.050 and WAC 246-945-015 through 246-945-017 or 246-933-340 (5)(a) and (b).

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-507, filed 6/1/20, effective 7/1/20.]

WAC 246-945-510 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Recordkeeping and reports. (1) Each registered humane society, animal control agency, and department of fish and wildlife chemical capture program location shall record the receipt, use, and disposition of approved drugs in a logbook or electronic record. An electronic record can meet the requirements of this section if the electronic record is legible and in a readily retrievable format, provided federal law does not require them to be kept in a hard copy format.

(2) The logbook or electronic record must have sufficient detail to allow an audit of the drug usage to be performed and must include:

(a) Date and time of administration;
(b) Route of administration;

(c) Identification number or other identifier assigned to the animal;

(d) Estimated weight of the animal;

(e) Estimated age and breed or species of the animal;

(f) Name of drug used;

(g) Dose of drug administered;

(h) Amount of drug wasted; and

(i) Initials of the primary person administering the drug.

(3) The logbook or electronic record may omit subsection (2)(b), (d), and (e) of this section if the information is recorded in other records cross-referenced by the animal identification number or other assigned identifier.

(4) Authorized personnel of the registered entity shall document any errors or discrepancies in the drug inventory in the logbook or electronic record and report to the registered entity for investigation.

(5) The registered entity shall report any unresolved discrepancies in writing to the commission within seven calendar days and to the DEA if the loss includes a controlled substance.

(6) The designated person shall perform a physical inventory or count of approved drugs every twelve months. The physical inventory must be reconciled with the logbook or electronic record.

(7) The designated person or designee shall destroy or waste noncontrolled legend drugs that are unfit for administration. A second member of the staff shall witness the destruction or waste of drugs. The destruction or waste of noncontrolled legend drugs will be documented in the logbook or electronic record with the date of the event and signatures of the individuals involved.

(8) A registered entity shall return all unwanted or unused approved controlled substances to the manufacturer or destroy them in accordance with the rules and requirements of the commission, the DEA, and the department of ecology. The return or destruction of controlled substances will be documented in the logbook or electronic record with the date of the event and signatures of the individuals involved.

(9) A registered entity must maintain a readily retrievable list of all authorized personnel who have demonstrated the qualifications to possess and administer approved drugs.

(10) All records of the registered entity must be available for inspection by the commission or its designee.

(11) The registered entity must maintain the logbook and other related records in accordance with WAC 246-945-020.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-510, filed 6/1/20, effective 7/1/20.]

WAC 246-945-515 Humane societies, animal control agencies, and department of fish and wildlife chemical capture programs—Drug storage and field use. (1) Each registered humane society, animal control agency, and department of fish and wildlife chemical capture program location must store all approved legend drugs, and approved controlled substances in a substantially constructed securely locked cabinet or drawer.

(2) Only authorized personnel as defined in WAC 246-945-503 (2) and (3) shall have access to the drug storage cabinet or drawer at the registered location.

(3) A registered humane society and animal control agency may allow the possession of approved drugs for field use under the following conditions:

(a) The individual meets the requirements of an authorized person in WAC 246-945-503(2);

(b) The individual is either:

(i) A humane officer;

(ii) An animal control enforcement officer;

(iii) An animal control authority; or

(iv) A peace officer authorized by the chief of police, sheriff, or county commissioner.

(c) The approved drugs are stored in a locked metal box securely attached to a vehicle;

(d) A drug inventory is completed at the beginning and end of each shift, and recorded in a logbook or electronic record that meets the requirements of WAC 246-945-510; and

(e) All receipts and use of approved drugs are recorded in a logbook or electronic record that meets the requirements of WAC 246-945-510.

(4) A registered department of fish and wildlife chemical capture program may allow the possession of approved drugs for field use under the following conditions:

(a) The individual meets the requirements of an authorized person in WAC 246-945-503(3);

(b) The approved drugs are stored in a locked metal box securely attached to a vehicle;

(c) A drug inventory is completed on a monthly basis and recorded in a logbook or electronic record that meets the requirements of WAC 246-945-510; and

(d) All receipts and use of approved drugs are recorded in a logbook or electronic record that meets the requirements of WAC 246-945-510.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-515, filed 6/1/20, effective 7/1/20.]

Subpart C – Drug Distributors

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., Part 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R., Part 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General."

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A), shall also comply with FDA guidance document.

(3) Virtual manufacturers shall ensure its own drugs are manufactured in compliance with this section.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-550, filed 6/1/20, effective 7/1/20.]

WAC 246-945-553 Teat dip containers. The reuse of teat dip containers and closures shall be allowed under the following circumstances:

(1) Teat dip containers for reuse must have attached a labeling panel bearing product name, brand name and distributor address if marketed by other than the manufacturer, manufacturer name and address, product strength, quantity, expiration date, directions for use, and appropriate cautionary statements for the product contained within.

(2) All reusable teat dip containers will be hot stamped for permanent identification as teat dip containers. The hot stamp shall imprint on the plastic container, in an immutable manner, the words "teat dip only" and the manufacturer's name. Teat dip manufacturers may only refill containers bearing their company name.

(3) With cooperation from dairy producers, dairy sanitarians will take random samples of teat dip in reusable containers while on regular farm inspections. The samples, along with appropriate label information, will be forwarded to the commission for analysis to ensure that the product meets label specifications and is free of contamination.

(4) Reusable teat dip containers shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quantity, or purity of the product.

(5) Upon return to the manufacturer, reusable teat dip containers shall be cleaned and sanitized. To ensure adequate cleaning occurs, the commission may require a manufacturer to submit and have approved a cleaning procedure. Containers showing structural damage, or any signs of being used for substances or materials other than teat dip shall not be reused as teat dip containers.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-553, filed 6/1/20, effective 7/1/20.]

WAC 246-945-555 Wholesaler—Minimum standards—Scope. (1) WAC 246-945-560 through 246-945-600 establish the minimum standards for facilities licensed as wholesalers, their officers, designated representatives, agents, and employees.

(2) Virtual wholesalers shall ensure drugs they purchase or sell are stored and distributed in compliance with WAC 246-945-560 through 246-945-600.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310,

18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-555, filed 6/1/20, effective 7/1/20.]

WAC 246-945-560 Wholesaler—Facility standards. (1) Facilities used for wholesale drug distribution must:

(a) Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;

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

(c) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

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

(e) Be free from infestation of any kind;

(f) Be a commercial location and not a personal dwelling or residence;

(g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information; and

(h) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs.

(2) Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:

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

(b) The outside perimeter of the premises must be well lit;

(c) Entry into areas where drugs are held must be limited to authorized personnel;

(d) Facilities must be equipped with an alarm system to detect entry after hours; and

(e) Facilities must be equipped with security systems sufficient to protect against theft, diversion, or record tampering.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-560, filed 6/1/20, effective 7/1/20.]

WAC 246-945-565 Wholesaler—Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF), to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

(2) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an

official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Temperature and humidity recording equipment, devices, and/or logs shall be used to document proper storage of drugs.

(4) Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area.

(5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.

(6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.

(7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-565, filed 6/1/20, effective 7/1/20.]

WAC 246-945-570 Wholesaler—Drug shipment inspection. (1) Each outside shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.

(2) Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-570, filed 6/1/20, effective 7/1/20.]

WAC 246-945-575 Wholesaler—Recordkeeping. (1) Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. The records must include at least:

(a) The source of the drugs, including the name and principal address of the seller or transferor;

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

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

(2) Records must be retained in a readily retrievable manner in accordance with WAC 246-945-020.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253,

18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-575, filed 6/1/20, effective 7/1/20.]

WAC 246-945-580 Wholesaler——Personnel. (1) A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications.

(2) A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-580, filed 6/1/20, effective 7/1/20.]

WAC 246-945-585 Wholesaler——Suspicious orders and due diligence. (1) Wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission.

(a) Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to:

(i) Customer name;

(ii) Customer address;

(iii) Customer DEA registration number;

(iv) State license number(s);

(v) Transaction date;

(vi) Drug name;

(vii) NDC number;

(viii) Quantity ordered; and

(ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.

(b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month.

(c) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

(2) Except as provided in subsection (3) of this section, a wholesaler shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary:

(a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it

shall be considered illegal for a customer to provide false or misleading information;

(b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) Review of drug utilization reports; and

(d) Obtaining and conducting a review of the following:

(i) Methods of payment accepted and in what ratios;

(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales;

(iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and

(iv) The ratio of out-of-state patients served compared to in-state patients.

(3) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection (2) of this section if all of the following apply:

(a) The sale is to a new customer;

(b) The wholesaler documents that the order is to meet an emergent need;

(c) The wholesaler completes the requirements of subsection (2) of this section no later than sixty business days from the date of sale.

(4) A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.

(5) Any customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell, shall be electronically reported to the commission. Such reports shall include:

(a) Customer name;

(b) Customer address;

(c) DEA number;

(d) State license number(s);

(e) A detailed explanation of why the wholesaler identified the customer as a possible diversion risk; and

(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.

(6) All licensed wholesalers shall submit all reports to the commission in a DEA ARCOS format where applicable.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-585, filed 6/1/20, effective 7/1/20.]

WAC 246-945-590 Wholesaler—Policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and pro-

cedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

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

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies as required to the FDA, commission and/or appropriate federal or state agency upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC 246-960-330; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-590, filed 6/1/20, effective 7/1/20.]

WAC 246-945-595 Wholesaler and manufacturer—Prohibited acts. It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state:

(1) The manufacture, repackaging, sale, delivery, or holding or offering for sale any drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

(2) The adulteration, misbranding, or counterfeiting of any drug;

(3) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the product labeling of a drug or the commission of any other act with respect to a drug that results in the drug being misbranded;

(4) The forging, counterfeiting, simulating, or falsely representing of any drug without the authority of the manufacturer, or using any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs to that purchaser or recipient;

(6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug;

(7) The sale or transfer of a drug from pharmacies to distributors for resale;

(8) The failure to maintain or provide records as required by laws and rules;

(9) Providing the commission or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of these laws and rules;

(10) The obtaining of or attempting to obtain a drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution or wholesale distribution of a drug;

(11) The distribution of a drug to the patient without a prescription from a practitioner licensed by law to use or prescribe the drug; and

(12) The distribution or wholesale distribution of a drug that was previously dispensed by a pharmacy or distributed by a practitioner.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-595, filed 6/1/20, effective 7/1/20.]

WAC 246-945-600 Salvaging and reprocessing. Wholesalers shall be subject to the provisions of any applicable federal, state, or lo-

cal laws or rules that relate to prescription drug salvaging or reprocessing, including Chapter 21, Parts 207, 210, and 211k of the Code of Federal Regulations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-600, filed 6/1/20, effective 7/1/20.]

WAC 246-945-990 Pharmaceutical licensing fees and renewal cycle. (1) Pharmacist, pharmacy technician, pharmacy intern, and pharmacy assistant credentials must be renewed every two years on the practitioner's birthday as provided in chapter 246-12 WAC.

(2) Pharmacy location credentials, controlled substance researcher registration, drug dog handler K9 registration, and other Controlled Substances Act registrations will expire on June 1st of each year.

(3) All other credentials, including health care entity, will expire on October 1st of each year, except the shopkeeper endorsement which expires annually associated with a business license issued by the department of revenue.

(4) The following nonrefundable fees will be charged for pharmacy professionals:

(a) All pharmacy professionals:

Title of fee	Fee
Verification of credential	$25.00
Duplicate credential	10.00

(b) Pharmacist:

Initial credential	$400.00
Renewal	530.00
Late renewal penalty	265.00
Expired credential reissuance	265.00
Inactive credential renewal	265.00
Retired active credential status application	50.00
Retired active credential status renewal	50.00
Temporary practice permit	100.00
Reciprocity (license by license transfer)	465.00

(c) Pharmacy technician:

Initial credential	$140.00
Renewal	140.00
Late renewal penalty	70.00
Expired credential reissuance	70.00

(d) Pharmacy intern:

Initial credential	$90.00
Renewal	90.00
Late renewal penalty	50.00
Verification of internship hours	25.00
Expired credential reissuance	45.00

(e) Pharmacy assistant:

Initial credential	$70.00
Renewal	70.00
Late renewal penalty	50.00
Expired credential reissuance	35.00

(5) The following nonrefundable fees will be charged for pharmaceutical firms:

(a) All pharmaceutical firms:

Verification of credential	$25.00
Duplicate credential	10.00
Facility inspection	400.00

(b) Pharmacy (includes hospital pharmacies):

Pharmacy credential (for hospital pharmacy associated clinics, see WAC 246-945-991)	
Initial credential	$540.00
Renewal	540.00
Late renewal penalty	270.00
Pharmacy technician utilization	
Initial utilization	100.00
Renewal	100.00
Controlled substances authority	
Initial credential	150.00
Renewal	150.00

(c) Nonresident pharmacy:

Pharmacy credential	
Initial credential	$540.00
Renewal	540.00
Late renewal penalty	270.00
Controlled substances authority	
Initial credential	150.00
Renewal	150.00

(d) Controlled substance researcher:

Initial credential	$400.00
Renewal	400.00

(e) Other controlled substances act registrations (i.e., analytical laboratories, school laboratories):

Initial credential	$360.00
Renewal	360.00

(f) Drug dog handler K9 registration:

Initial credential	$55.00
Renewal	55.00

(g) Health care entity:

Health care entity credential	
Initial credential	$540.00
Renewal	540.00

Late renewal penalty	270.00
Controlled substances authority	
Initial credential	150.00
Renewal	150.00

(h) Drug manufacturer:

Manufacturer credential	
Initial credential	$825.00
Renewal	825.00
Late renewal penalty	300.00
Controlled substances authority	
Initial credential	150.00
Renewal	150.00

(i) Drug wholesaler - Full line:

Wholesaler credential	
Initial credential	$825.00
Renewal	825.00
Late renewal penalty	300.00
Controlled substances authority	
Initial credential	150.00
Renewal	150.00

(j) Drug wholesaler - Export:

Wholesaler credential	
Initial credential	$825.00
Renewal	825.00
Late renewal penalty	300.00

(k) Drug wholesaler - OTC only:

Initial credential	$465.00
Renewal	465.00
Late renewal penalty	235.00

(l) Drug wholesaler - Export nonprofit humanitarian organization:

Wholesaler credential	
Initial credential	$25.00
Renewal	25.00
Late renewal penalty	25.00

(m) Legend drug sample distributor:

Distributor credential	
Initial credential	$540.00
Renewal	540.00
Late renewal penalty	270.00
Controlled substances authority	
Initial credential	150.00
Renewal	150.00

(n) Poison manufacturer/seller:

Initial credential	$55.00

Renewal	55.00
Late renewal penalty	50.00

(o) Precursor chemicals:

Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(p) Itinerant vendor:

Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(q) Sodium pentobarbital for animal euthanization:

Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

(r) Shopkeeper:

Initial credential	$55.00
Renewal	55.00

(s) Remote dispensing site for opioid use disorder medications registration:

Initial credential	$55.00
Renewal	55.00
Late renewal penalty	50.00

[Statutory Authority: RCW 43.70.110, 43.70.250 and 2020 c 244. WSR 21-18-102, amended and recodified as § 246-945-990, filed 8/31/21, effective 12/1/21. Statutory Authority: RCW 43.70.250, 43.70.280 and chapters 18.64 and 18.64A RCW. WSR 18-21-123, § 246-907-030, filed 10/18/18, effective 1/1/19. Statutory Authority: RCW 69.50.302, 43.70.250. WSR 16-18-087, § 246-907-030, filed 9/6/16, effective 10/7/16. Statutory Authority: RCW 43.70.110, 43.70.250, and 2011 1st sp.s. c 50. WSR 11-20-092, § 246-907-030, filed 10/4/11, effective 12/1/11. Statutory Authority: RCW 43.70.110, 43.70.250, 2008 c 329. WSR 08-15-014, § 246-907-030, filed 7/7/08, effective 7/7/08. Statutory Authority: RCW 43.70.250, [43.70.]280 and 43.70.110. WSR 05-12-012, § 246-907-030, filed 5/20/05, effective 7/1/05. Statutory Authority: RCW 43.70.250, 2001 2nd sp.s. c 7 and RCW 18.64.310, 18.64A.010. WSR 01-23-101, § 246-907-030, filed 11/21/01, effective 1/21/02. Statutory Authority: RCW 43.70.040, 42.70.250, and 18.64.310. WSR 01-12-052, § 246-907-030, filed 6/1/01, effective 7/2/01. Statutory Authority: RCW 43.70.250. WSR 98-10-052, § 246-907-030, filed 4/29/98, effective 5/30/98. Statutory Authority: RCW 43.70.280. WSR 98-05-060, § 246-907-030, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 43.70.040. WSR 97-06-019, § 246-907-030, filed 2/25/97, effective 3/28/97. Statutory Authority: RCW 18.64.005. WSR 94-05-036, § 246-907-030, filed 2/8/94, effective 3/11/94; WSR 93-18-015, § 246-907-030, filed 8/24/93, effective 9/24/93; WSR 93-05-045 (Order 334), § 246-907-030, filed 2/17/93, effective 3/20/93. Statutory Authority: RCW 43.70.250. WSR 92-07-099 (Order 256), § 246-907-030, filed 3/18/92, effective 4/18/92. Statutory Authority: RCW 43.70.040.

WSR 91-19-028 (Order 194), recodified as § 246-907-030, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 43.70.250. WSR 91-13-002 (Order 173), § 360-18-020, filed 6/6/91, effective 7/7/91. Statutory Authority: RCW 18.64.005. WSR 89-04-015 (Order 222), § 360-18-020, filed 1/23/89; WSR 88-14-042 (Order 216), § 360-18-020, filed 6/30/88; WSR 88-07-011 (Order 209), § 360-18-020, filed 3/3/88; WSR 87-18-066 (Order 207), § 360-18-020, filed 9/2/87. Statutory Authority: RCW 18.64.005(4). WSR 85-22-033 (Order 196), § 360-18-020, filed 10/31/85; WSR 85-06-010 (Order 193), § 360-18-020, filed 2/22/85. Statutory Authority: RCW 18.64.005. WSR 84-17-142 (Order 189), § 360-18-020, filed 8/22/84; WSR 84-04-030 (Order 184), § 360-18-020, filed 1/25/84; WSR 83-22-034 (Order 177), § 360-18-020, filed 10/26/83. Statutory Authority: RCW 18.64.005 and 18.64A.020. WSR 83-18-021 (Order 175), § 360-18-020, filed 8/30/83. Statutory Authority: RCW 18.64.005(12). WSR 82-12-041 (Order 168), § 360-18-020, filed 5/28/82. Statutory Authority: RCW 18.64.005 (4) and (11). WSR 80-08-035 (Order 155, Resolution No. 6/80), § 360-18-020, filed 6/26/80, effective 9/30/80; WSR 80-05-074 (Order 154, Resolution No. 4/80), § 360-18-020, filed 4/28/80.]

WAC 246-945-991 Hospital pharmacy associated clinics fees and renewal cycle. (1) Parent hospital pharmacy licenses with one or more hospital pharmacy associated clinics (HPAC) expire on June 1st of each year.

(2) A parent hospital pharmacy must submit fees for HPACs in addition to fees set in WAC 246-945-990(5). HPAC fees are due annually, except as provided under subsection (3)(d) of this section.

(3) A parent hospital pharmacy must submit the following nonrefundable fees based on category and number of HPACs as defined in WAC 246-945-233(3) added to the parent hospital pharmacy license.

(a) **Category 1 HPAC.** A parent hospital pharmacy must submit the Category 1 HPAC fee according to the number of Category 1 HPACs under the parent hospital pharmacy license.

HPAC tier	Number of Category 1 HPACs under parent hospital pharmacy license	Total annual fee
A	1-10	$895.00
B	11-50	$2,240.00
C	51-100	$3,125.00
D	Over 100	$4,025.00

(b) **Category 2 HPAC.** A parent hospital pharmacy must submit the Category 2 HPAC fee for each Category 2 HPAC under the parent hospital pharmacy license.

Category 2 HPAC fee	$755.00

(c) The department charges a processing fee of fifty-five dollars for an amended license to change the number of HPACs.

(d) If at any time a parent hospital pharmacy submits an addendum increasing the number of HPACs on the parent hospital pharmacy license, which changes the applicable HPAC tier to a higher fee amount, the parent hospital pharmacy shall submit the difference in fees with the addendum.

(e) The department will not refund fees when a tier reduction occurs between renewal periods.

[Statutory Authority: RCW 43.70.110, 43.70.250 and 2020 c 244. WSR 21-18-102, amended and recodified as § 246-945-991, filed 8/31/21, effective 12/1/21. Statutory Authority: RCW 43.70.250, 43.70.280 and chapters 18.64 and 18.64A RCW. WSR 18-21-123, § 246-907-0302, filed 10/18/18, effective 1/1/19. Statutory Authority: RCW 43.70.250 and 2016 c 118. WSR 16-18-069, § 246-907-0302, filed 9/2/16, effective 9/8/16.]

WAC 246-945-992 Fee payment. (1) A licensed pharmacy, wholesaler, or manufacturer shall pay a facility inspection fee in lieu of the original license fee when there is only a change of facility location within the premises identified by the license address. Any change of location to a different address shall require a new application and payment of the original license fee.

(2) An original license fee shall be paid whenever there is any change in ownership, including change in business structure or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than fifty percent ownership in a corporation.

(3) All fees for pharmacy professionals are charged on a biennial basis and will not be prorated.

(4) All fees for pharmaceutical firms are charged on an annual basis and will not be prorated.

[Statutory Authority: RCW 43.70.110, 43.70.250 and 2020 c 244. WSR 21-18-102, amended and recodified as § 246-945-992, filed 8/31/21, effective 12/1/21. Statutory Authority: RCW 43.70.040. WSR 91-19-028 (Order 194), recodified as § 246-907-040, filed 9/10/91, effective 10/11/91. Statutory Authority: RCW 18.64.005. WSR 88-07-011 (Order 209), § 360-18-025, filed 3/3/88.]