Part 1 – General Provisions

WAC 246-945-001 Definitions

The definitions in RCW 18.64.011 and those in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) “ACPE” means Accreditation Council for Pharmacy Education.

(2) “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 current good manufacturing practice to assure that such drug meets the requirement of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(3) “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.

(4) “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.

(5) “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.

(6) “Chemical Capture Program” means wildlife management programs registered under RCW 69.50.320 and 69.41.080 to use approved legend drugs and controlled substances 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.

(7) “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.

(8) “Controlled Substances” has the same meaning as RCW 69.50.101.

(9) “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.

(10) “Commission” means the Pharmacy Quality Assurance Commission.
“CPE” means continuing pharmacy education accredited by the ACPE.

“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.

“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.

“DEA” means the United States Drug Enforcement Administration.

“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.

“Department” means the Washington State Department of Health.

“Drug(s) of Concern” are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense such substances in this state.

“Drug Advertising” means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

“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.

“Drug standard and information sources” means industry recognized reference and resources.

“Drug storage area” means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

“Drug Utilization Review” includes, but is not limited to, the following activities:
(1) Evaluation of prescription drug orders and patient records for known allergies, rational therapy-contraindications, appropriate dose and route of administration and appropriate directions for use;
(2) Evaluation of prescription drug orders and patient records for duplication of therapy;
(3) Evaluation of prescription drug orders and patient records for interactions between drug-drug, drug-food, drug-disease and adverse drug reactions; and
(4) Evaluation of prescription drug orders and patient records for proper utilization, including over-or under-utilization, and optimum therapeutic outcomes.

(18) “Electronic means” An electronic device used to send, receive, and/or store prescription drug order information, including computers, facsimile machines, etc.

(19) “Enrolled” 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.

(20) “Equivalent Manager” means an individual authorized to act on behalf of the covered entity 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.

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

(22) “FDA” – United States Food and Drug Administration

(23) “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.

(24) “FPGE” means Foreign Pharmacy Graduate Examination Committee.

(25) “FPGEE” means Foreign Pharmacy Graduate Equivalency Examination

(26) “Generic Substitution” means the act of switching between a branded drug and its therapeutically equivalent generic version.

(27) “Hospital” means any institution licensed under chapters 70.41 or 71.12 RCW or designated under RCW 72.23.020.
"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.

"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.

"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.

"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 healthcare professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.
"Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

“Investigational drug” means any article that has an investigational drug application (IND) has been approved by the FDA.

“Misbranded” applies to all drugs or articles of food, or articles which enter into the composition of food, 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, and to any food or drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

“MPJE” the Multistate Pharmacy Jurisprudence Examination for Washington.

“NABP” means the National Association of Boards of Pharmacy.

“NDC” means National Drug Code

“Nuclear pharmacy” means a pharmacy providing radiopharmaceutical services.

“Nuclear pharmacist” means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

“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.

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

“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

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

“Pharmacy Intern” means a person who files with the department an application for registration as a pharmacy intern.

“Pharmacy Services” means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.
“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.

“Precursor Drugs” as defined in chapter 69.43 RCW.

“Prescription” is defined to include order.

“Prescription drug” means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, 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.

“Protocol” means a written set of guidelines.

“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; the maintenance of radiopharmaceutical quality assurance;
(d) the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or
(e) the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

“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’.
"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.

"Readily Retrievable" means a record that is kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that it can be separated out from all other records in a reasonable time.

"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™)

"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.

"Secretary" means the secretary of the Washington State Department of Health.

"Standard of Care" means acting as a reasonable person, similarly licensed, educated, trained, experienced, and working in similar circumstances or practice setting.

"US 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.

"USP" mean the United State Pharmacopeia.

"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.

"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.

"Virtual Manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.
“Virtual Wholesaler” means an individual or facility that sells a prescription drug and/or device, but never physically possesses the product.

“Wholesale Distribution” means the distribution of a drug to a person other than a consumer or patient, or receipt of a drug by a person other than the consumer or patient, but does not include:

(a) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;
(b) The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;
(c) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
(d) The dispensing of a drug pursuant to a prescription;
(e) The distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;
(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
(g) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;
(h) The distribution of a drug by the manufacturer of such drug;
(i) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;
(j) Salable drug returns when conducted by a dispenser;
(k) The distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a “medical convenience kit”) if--
   (i) The medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 360(b)(2) of this title;
   (ii) The medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;
   (iii) In the case of a medical convenience kit that includes a product, the person that manufacturers the kit--
      (I) Purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and
      (II) Does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and
   (iv) In the case of a medical convenience kit that includes a product, the product is--

Commented [GCO(4): New definition from Chris, mirrors a federal definition]
(I) An intravenous solution intended for the replenishment of fluids and electrolytes;
(II) A product intended to maintain the equilibrium of water and minerals in the body;
(III) A product intended for irrigation or reconstitution;
(IV) An anesthetic;
(V) An anticoagulant;
(VI) A vasopressor; or
(VII) A sympathomimetic;

(l) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
(m) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
(n) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection; or
(a) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments.

Subpart A – Commission Operations

WAC 246-945-002 Administrative Proceedings and Appeals

(1) The commission adopts the model procedural rules for administrative proceedings boards as adopted by the department, and contained in chapter 246-11 WAC, including subsequent amendments, under chapter 246-11 WAC, unless otherwise addressed in rules adopted by the commission.

(2) The commission adopts the model procedural rules for credentialing administrative procedures and requirements for credentialed health care providers as adopted by the department and contained in chapter 246-12 WAC, including subsequent amendments under chapter 246-12 WAC, unless otherwise addressed in rules adopted by the commission.

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

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 equivalent manager, or designee(s), 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 designee, 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 designee, 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 credential holder or 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 credential holder or 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.

Commented [GCO(5)]: Suggest deleting designee, could still choose to delegate this work but the RPM would be the one responsible for the information

Commented [GCO(6)]: Credential holder is defined above to mean a person, so it would no longer apply in this section
(d) The Commission shall consider any dispute and notify the credential holder or pharmaceutical firm of its determination.

(6) Investigations. A credential holder or 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.

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) A prescription for a non-controlled 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 signature, or prescriber’s authorized agent signature if allowed by law; and
   (i) If the prescription written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(3) 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.

(4) 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.

(5) For the purposes of this section the signature of a prescriber or prescriber’s authorized agent shall be an electronic or digital signature for prescriptions or chart orders transmitted electronically, and shall be a printed or wet signature of a prescriber or prescriber’s authorized agent for written prescriptions.

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 and the date of dispensing is more than six months after the prescription’s date of issue,
   (b) The prescription is for a controlled substance listed in Schedules III, IV, or V and the date of dispensing is more than six months after the prescription’s date of issue,
   (c) The prescription is for a non-controlled legend drug and the date of dispensing is more than twelve months after the prescription’s date of issue.

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 after six months from the date of issue pursuant to WAC 246-945-011 even if there are refills remaining.
(3) A prescription for a non-controlled legend drug may be refilled as indicated by the prescriber. 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.

WAC 246-945-013 Partial Filling of Prescriptions

(1) A pharmacist may partially fill a prescription for non-controlled legend drugs and controlled substances listed in Schedule III-V provided that:
   (a) The partial fill is required 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-V comply with 21 C.F.R. 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. § 829, and 21 C.F.R. § 1306.13.

WAC 246-945-014 Dispensing of Drugs without a Prescription

(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) Except as provided in subsection (1) of this section, 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”.  

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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.

(3) Except as provided in subsection (1) of this section, 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.

(4) Except as provided in subsection (1) of this section, a non-controlled 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 non-controlled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

WAC 246-945-015 Prescriptions – Labels – Minimum Requirements for Dispensing Practitioners

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.

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, RCW 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 the patient is an animal; and
   (e) The name of the facility or entity authorized 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 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.

**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. Accessory or cautionary statements and the expiration date shall be applied to containers as appropriate.

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

**WAC 246-945-018 Prescriptions: Labeling – Prepackage Product**

Prepackaged drugs must include a label with the following information;

(1) drug name,
(2) drug strength,
(3) expiration date,
(4) the manufacturer’s name and lot number, and
(5) the identity of the pharmacist or provider responsible for the prepackaging. If not maintained in a separate record.

**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.

**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.

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

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

(5) 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.

(6) Upon request from the patient, no pharmacy shall refuse to disclose the cost to the specific patient of a prescription drug.

(6) A pharmacy shall refuse to disclose the cost to the patient price of a prescription drug upon request by a consumer.

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 and listed in at least one of the following publications:


(3) Copies of the reference material listed in subsection (2) are available for public inspection at the Commission’s office at Department of Health, Town Center 2, 111 Israel Road SE, 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.

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:

<table>
<thead>
<tr>
<th>TRADE NAME</th>
<th>CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMESAC capsule</td>
<td>25 mg. ephedrine (Russ)</td>
</tr>
<tr>
<td>AZMA AID tablet</td>
<td>24 mg. ephedrine (Various, eg Purepac)</td>
</tr>
</tbody>
</table>

Commented [GCO(10): Moved up from 036 no other changes]
<table>
<thead>
<tr>
<th>No.</th>
<th>Product Name</th>
<th>Active Ingredient</th>
<th>Manufacturer/Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>BRONC-EASE PLUS (Natur-Pharma)</td>
<td>25 mg. ephedrine HCL</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>BRONCHODILATOR AND EXpectorant (PDK Labs)</td>
<td>25 mg. ephedrine HCL</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>BRONITIN tablet (Whitehall)</td>
<td>24 mg. ephedrine HCL</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>BRONKAIID tablet (Breon)</td>
<td>24 mg. ephedrine sulfate</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>BRONKOLIXER (Sterling Winthrop)</td>
<td>12 mg. ephedrine</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>BRONKOTABS tablet (Breon)</td>
<td>24 mg. ephedrine sulfate</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>EFEDRON nasal jelly (Hyrex)</td>
<td>0.6% ephedrine HCL in 20 g.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>MINI THINS asthma relief (BDI Pharmaceuticals)</td>
<td>25 mg. ephedrine</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>PAZO HEMORRHOID suppositor (Bristol-Meyers)</td>
<td>3.86 mg. ephedrine sulfate</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>PAZO HEMORRHOID ointment (Bristol-Meyers)</td>
<td>0.2% ephedrine sulfate</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>PRIMATENE tablet (Whitehall)</td>
<td>24 mg. ephedrine HCL</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>PRIMATENE M tablet (Whitehall)</td>
<td>24 mg. ephedrine HCL</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>PRIMATENE P tablet (Whitehall)</td>
<td>24 mg. ephedrine HCL</td>
<td></td>
</tr>
<tr>
<td>Product Name</td>
<td>Active Ingredient</td>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------</td>
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<td></td>
</tr>
<tr>
<td>QUELIDRINE (Abbott)</td>
<td>5 mg. ephedrine HCL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEDRAL tablet (Parke-Davis)</td>
<td>24 mg. ephedrine HCL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>THEODRINE tablet (Rugby)</td>
<td>25 mg. ephedrine HCL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VATRONOL nose drops (Vicks Health Care)</td>
<td>0.5% ephedrine sulfate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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:

- Provides the commission with the formulation of any such product;
- 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
- Receives the commission’s approval to market such product.

**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 C.F.R. Part 1700 of Title 16, unless:

- 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.

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.

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.

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) dehydrochloromethyl-testosterone
(20) Delatestyl
(21) Dianabol
(22) Dihydroclone

WAC 246-945-038 Theophylline prescription restrictions

(1) The commission, under RCW 69.41.075, identifies theophylline, or any of its salts in a solid or liquid form normally intended for oral administration in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.
(2) Products containing 130 mg or less of theophylline per solid dosage unit or 130 mg or less per 5 ml of liquid forms, are not considered a legend drug and where the product contains other recognized therapeutic ingredients, may be sold or distributed without a prescription.
(3) Products with theophylline as the only active ingredient are identified as legend drugs.

WAC 246-945-038 Availability and Identity of Amygdaline

(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.

WAC 246-945-040 Uniform Controlled Substance Act
(1) The commission adopts Title 21 of the Code of Federal Regulations as its own. The following sections do not apply: Section 1301.13, section 1301.33, section 1301.35-.46, section 1303, section 1308.41-.45, and section 1316.31-.67. Any inconsistencies between Title 21 of the Code of Federal Regulations sections 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. 1301.12, where controlled substances are manufactured, distributed or dispensed. Application for registration must be made on forms supplied by the commission, 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. 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. 1307.11.
Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.

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.

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.

**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.

**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):
2. Multiple sclerosis; and
(3) Moderate to severe binge eating disorder in adults.

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.

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).

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) Dextrophan;

(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,
esters, 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,
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;

(j) Proheptazine.

(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: Methylhydromorphone.

(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-MBDD;

(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: Methyleneone;
(q) 3,4-Methylenedioxy-N-ethylamphetetamine; some other names: N-ethyl-alpha-methyl-3,4(methylenedioxy)-phenethylamine, N-ethyl MDA, MDE, and MDEA;
(r) 3,4-Methylenedioxyxpyrovalerone; 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-methoxymphetamine; some other names: 4-methoxy-alpha-methylphenethylamine; paramethoxymphetamine, PMA;
(u) 4-methyl-2,5-dimethoxyamphetamine;  
(v) 4-methyl-2,5-dimethoxyamphetamine; 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-1phenylethcyclohexylamine, (1-phenylethcyclohexyl) ethylamine; N-(1-phenylethcyclohexyl)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-phenylethyl)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 norephedrine;  

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(b) N,N-dimethylamphetamine; some other names: N,N-alpha-trimethylbenzeneethanamine; and N,N-alpha-trimethylphen ethylene.

(5) Cannabinimimetic agents and synthetic cannabinoids. Any of the following synthetic 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](napthalen-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)-benzoyle]indole; some other names: SR-19 and RCS-4;
(p) 1-pentyl-3-[1-(4-methoxyphosphthoyl)]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-API; 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;
(H) 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.

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) $^{123}$Iioflupane.

(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(δ) 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-dimethheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[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).

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.
(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.

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 salt 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);
(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
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Company</th>
<th>Form</th>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andro-Estro 90-4</td>
<td>Rugby Laboratories, Rockville Centre, NY</td>
<td>Vial</td>
<td>Testosterone enanthate; Estradiol valerate</td>
<td>90 mg/mL; 4 mg/mL</td>
</tr>
<tr>
<td>Androgyn L.A.</td>
<td>Forest Pharmaceuticals, St. Louis, MO</td>
<td>Vial</td>
<td>Testosterone enanthate; Estradiol valerate</td>
<td>90 mg/mL; 4 mg/mL</td>
</tr>
<tr>
<td>Component E-H</td>
<td>Ivy Laboratories, Inc., Overland Park, KS</td>
<td>Pail or drum</td>
<td>Testosterone propionate; Estradiol benzoate</td>
<td>10 parts; 1 part</td>
</tr>
<tr>
<td>Component E-H</td>
<td>Ivy Laboratories, Inc., Overland Park, KS</td>
<td>Pail</td>
<td>Testosterone propionate; Estradiol benzoate</td>
<td>25 mg/2.5 mg/pellet</td>
</tr>
<tr>
<td>Component TE-S</td>
<td>Ivy Laboratories, Inc., Overland Park, KS</td>
<td>Pail or drum</td>
<td>Trenbolone acetate; Estradiol USP</td>
<td>5 parts; 1 part</td>
</tr>
<tr>
<td>Component TE-S</td>
<td>Ivy Laboratories, Inc., Overland Park, KS</td>
<td>Pail</td>
<td>Trenbolone acetate; Estradiol USP</td>
<td>120 mg/24 mg/pellet</td>
</tr>
<tr>
<td>depANDROGYN</td>
<td>Forest Pharmaceuticals, St. Louis, MO</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Company</td>
<td>Form</td>
<td>Ingredients</td>
<td>Quantity</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------</td>
<td>--------</td>
<td>--------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Depo-Testadiol</td>
<td>The Upjohn Company, Kalamazoo, MI</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>depTESTROGEN</td>
<td>Martica Pharmaceuticals, Phoenix, AZ</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>DEPTO-T.E.</td>
<td>Quality Research Pharm., Carmel, IN</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Duomone</td>
<td>Wintec Pharmaceutical, Pacific, MO</td>
<td>Vial</td>
<td>Testosterone enanthate; Estradiol valerate</td>
<td>90 mg/mL; 4 mg/mL</td>
</tr>
<tr>
<td>DUO-SPAN II</td>
<td>Primedics Laboratories, Gardena, CA</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>DURATESTRIN</td>
<td>W. E. Hauck, Alpharetta, GA</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Essian</td>
<td>Pharmaceutics International Inc., Hunt Valley, MD</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Essian H.S.</td>
<td>Pharmaceutics International Inc.,</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Company</td>
<td>Form</td>
<td>Ingredients</td>
<td>Quantity</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>------------------------</td>
<td>------</td>
<td>------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg)</td>
<td>Interpharm, Inc.</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg)</td>
<td>Interpharm, Inc.</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Esterified Estrogens/ Methyltestosterone, (0.625 mg/1.25 mg) Tablet</td>
<td>ANDAPharm, LLC</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>Esterified Estrogens/ Methyltestosterone, (1.25 mg/2.5 mg) Tablet</td>
<td>ANDAPharm, LLC</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Estratex</td>
<td>Solvay Pharmaceuticals, Marietta, GA</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Estratex H.S.</td>
<td>Solvay Pharmaceuticals, Marietta, GA</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>Masculinizing Feed for Fish (Investigational)</td>
<td>Rangen, Inc., Buhl, ID</td>
<td>Plastic Bags</td>
<td>Methyltestosterone</td>
<td>60 mg/kg fish feed</td>
</tr>
<tr>
<td>Menogen</td>
<td>Sage Pharmaceuticals, Shreveport, LA</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Menogen HS</td>
<td>Sage Pharmaceuticals, Shreveport, LA</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Company</td>
<td>Form</td>
<td>Ingredients</td>
<td>Quantity</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------------------------</td>
<td>--------</td>
<td>------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg)</td>
<td>Lannett Company, Inc.</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Methyltestosterone and Esterified Estrogens (Half Strength) (1.25 mg/0.625 mg)</td>
<td>Lannett Company, Inc.</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>PAN Estra Test</td>
<td>Pan American Labs; Covington, LA</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Premarin with Methyltestosterone</td>
<td>Ayerst Labs Inc., New York, NY</td>
<td>TB</td>
<td>Conjugated estrogens; Methyltestosterone</td>
<td>0.625 mg; 5.0 mg</td>
</tr>
<tr>
<td>Premarin with Methyltestosterone</td>
<td>Ayerst Labs Inc., New York, NY</td>
<td>TB</td>
<td>Conjugated estrogens; Methyltestosterone</td>
<td>1.25 mg; 10.0 mg</td>
</tr>
<tr>
<td>Synovex H in-process bulk pellets</td>
<td>Syntex Animal Health, Palo Alto, CA</td>
<td>Drum</td>
<td>Testosterone propionate; Estradiol benzoate</td>
<td>25 mg; 2.5 mg/pellet</td>
</tr>
<tr>
<td>Synovex H in-process granulation</td>
<td>Syntex Animal Health, Palo Alto, CA</td>
<td>Drum</td>
<td>Testosterone propionate; Estradiol benzoate</td>
<td>10 part; 1 part</td>
</tr>
<tr>
<td>Synovex Plus in-process bulk pellets</td>
<td>Fort Dodge Animal Health, Fort Dodge, IA</td>
<td>Drum</td>
<td>Trenbolone acetate; Estradiol benzoate</td>
<td>25 mg; 3.5 mg/pellet</td>
</tr>
<tr>
<td>Synovex Plus in-process granulation</td>
<td>Fort Dodge Animal Health, Fort Dodge, IA</td>
<td>Drum</td>
<td>Trenbolone acetate; Estradiol benzoate</td>
<td>25 parts; 3.5 parts</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Company</td>
<td>Form</td>
<td>Ingredients</td>
<td>Quantity</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------</td>
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<td>--------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Syntest D.S.</td>
<td>Syntho Pharmaceuticals, Inc.</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>1.25 mg; 2.5 mg</td>
</tr>
<tr>
<td>Syntest H.S.</td>
<td>Syntho Pharmaceuticals, Inc.</td>
<td>TB</td>
<td>Esterified estrogens; Methyltestosterone</td>
<td>0.625 mg; 1.25 mg</td>
</tr>
<tr>
<td>TEST-ESTRO Cypionates</td>
<td>Rugby Laboratories, Rockville Centre, NY</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Testoderm 4 mg/d</td>
<td>Alza Corp., Palo Alto, CA</td>
<td>Patch</td>
<td>Testosterone</td>
<td>10 mg</td>
</tr>
<tr>
<td>Testoderm 6 mg/d</td>
<td>Alza Corp., Palo Alto, CA</td>
<td>Patch</td>
<td>Testosterone</td>
<td>15 mg</td>
</tr>
<tr>
<td>Testoderm in-process film</td>
<td>Alza Corp., Palo Alto, CA</td>
<td>Sheet</td>
<td>Testosterone</td>
<td>0.25 mg/cm²</td>
</tr>
<tr>
<td>Testoderm with Adhesive 4 mg/d</td>
<td>Alza Corp., Palo Alto, CA</td>
<td>Patch</td>
<td>Testosterone</td>
<td>10 mg</td>
</tr>
<tr>
<td>Testoderm with Adhesive 6 mg/d</td>
<td>Alza Corp., Palo Alto, CA</td>
<td>Patch</td>
<td>Testosterone</td>
<td>15 mg</td>
</tr>
<tr>
<td>Testoderm with Adhesive in-process film</td>
<td>Alza Corp., Palo Alto, CA</td>
<td>Sheet</td>
<td>Testosterone</td>
<td>0.25 mg/cm²</td>
</tr>
<tr>
<td>Testosterone Cyp 50 Estradiol Cyp 2</td>
<td>I.D.E.-Interstate, Amityville, NY</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Company</td>
<td>Form</td>
<td>Ingredients</td>
<td>Quantity</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------------</td>
<td>------</td>
<td>-------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Testosterone Cypionate/Estradiol</td>
<td>Best Generics, North Miami Beach, FL</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Cypionate Injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testosterone Cypionate/Estradiol</td>
<td>Goldline Labs, Ft. Lauderdale, FL</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Cypionate Injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testosterone Cypionate/Estradiol</td>
<td>Schein Pharmaceuticals, Port Washington, NY</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Cypionate Injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testosterone Cypionate/Estradiol</td>
<td>Steris Labs Inc., Phoenix, AZ</td>
<td>Vial</td>
<td>Testosterone cypionate; Estradiol cypionate</td>
<td>50 mg/mL; 2 mg/mL</td>
</tr>
<tr>
<td>Cypionate Injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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-dephenylethane)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.

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

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

Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols, also known as Epidiolex.

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.

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 (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.

(3) Precursor substances in subsection (1) (a) and (b) of this section are also regulated as schedule II immediate precursors pursuant to WAC 246-945-053. Registrants shall comply with all applicable rules and laws governing the distribution of schedule II controlled substances.

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.

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.

**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 board of pharmacy.
Any individual sale or transfer of a regulated product that exceeds ten percent of the nonprescription drugs contained in the order. [Example: If a wholesaler sells three thousand dollars worth of products to a shopkeeper and that order contains one thousand dollars worth of nonprescription drugs, the wholesaler must submit a suspicious transaction report if the order contains over one hundred dollars worth of regulated products.]

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

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;
(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;
(i) Lot number if available; and
(k) National Drug Code Number if available.

A pharmacy shall report to the commission, the DEA, the executive officer of the hospital and other appropriate authorities significant losses or disappearances of controlled substances and the facts surrounding the discrepancy.

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.

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

**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; and
(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.

(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.

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.

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 uses 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.

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 board, 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).

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

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.

Subpart D – Home Dialysis

WAC 246-945-090 Home Dialysis Program – Legend Drugs

(1) 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:
   (a) Sterile heparin, 1000u/ml, in vials;
   (b) Sterile potassium chloride, 2mEq/ml, for injection;
   (c) Commercially available dialysate; and,
   (d) Sterile sodium chloride, 0.9%, for injection in containers of not less than 150ml.

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.

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.

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.

Part 2 – General Licensing

WAC 246-945-145 License Required
An individual providing pharmacy services to Washington residents 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 licensed nonresident pharmacy or the law otherwise permits the practice.

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, and pay all applicable fees in WAC 246-945-290.

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

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(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; or
(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.

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 WAC 246-945-290.

(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 (90) after the temporary practice permit is issued.

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 fifteen hundred 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 English as a Foreign Language test;
   (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 fifteen hundred 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.

(4) An applicant for a pharmacist license shall provide proof of completion of seven hours of AIDS education as required in chapter 246-12 WAC, Part 8. The applicant is exempt from this requirement if they are a graduate of a commission accredited school or college of pharmacy because the curriculum satisfies this requirement.
WAC 246-945-163 Certification of Internship Hours

Hours reported to the commission under WAC 246-945-162, WAC 246-945-173 and WAC 246-945-175, shall occur as follows:

1. From a commission accredited school or college of pharmacy or the supervising pharmacist at the internship site.

2. Hours shall be reported thirty days after the completion of any internship experience.

3. The documentation must include the supervising pharmacist’s evaluation and certification of internship hours, and an intern site evaluation.

4. 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.

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 75 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.

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 state 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 (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, and
(b) Does not have a criminal record in Washington state; and
(c) The applicant’s fingerprint-based national background check results are pending.
(d) To request a temporary practice permit, the applicant shall submit a written request for a temporary practice permit, and pay applicable fees in accordance with WAC 246-945-290.

(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.

**WAC 246-945-173 Expired Pharmacist License**

To return to active status a pharmacist with an expired license shall pay the applicable fees in WAC 246-945-290 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 15 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 WAC 246-12, 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.

(b)(c) Submit proof of an active credential 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 state, the pharmacist shall:

(a) Meet the requirements of chapter 246-12, Part 2;
(b) Serve an internship of 300 hours in compliance with WAC 246-945-163; and
(c) Take and pass the commission approved jurisprudence and licensure examinations.

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 WAC 246-945-290.

(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 state 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) Provide documentation of active practice from another state within the last three years. Submit verification of current active pharmacy practice 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 state, to return to active status, the pharmacist shall comply with the requirements of WAC 246-945-173(3).
WAC 246-945-178 Pharmacist Continuing Education

(1) As part of the process to renew a pharmacist license, a pharmacist shall complete continuing pharmacy education (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) The training is at least three hours long;

   (b) The training shall 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.

   (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.

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.

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 meet the requirements of chapter 246-12 WAC, Part 2.

(2) An initial applicant shall provide proof of four hours of AIDS education as required in chapter 246-12 WAC, Part 8.

(3) The supervising pharmacist, shall instruct the pharmacy assistant regarding their scope of practice.
(4) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with WAC 246-945-290.

**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.

**WAC 246-945-205 Pharmacy Technician Certification**

(1) An applicant for a pharmacy technician certification shall be 18 years of age and a 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 four hours of AIDS education as required in chapter 246-12 WAC, Part 8, the applicant is exempt if they have completed a commission-approved training program whose program materials on file with the commission office document four hours of AIDS education.

(c) Provide proof of successful completion of a commission approved pharmacy-technician training program. 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 one-year diploma or certification 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.

(d) 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, a test of English as a Foreign Language;

   (b) Complete 520 hours of supervised experience under the supervision of a license 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. The commission must approve training programs approved in other states.
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.

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) The United States Armed Forces; or
(d) Any U.S. jurisdiction board or commission that licenses pharmacy technicians.

(2) A pharmacy technician education and training program not covered by (1), shall be 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, and regulations, guidelines and interpretive statements; and

Commented [GCO(32): No tech temporary practice permits for anyone other than military, is this something the commission wants, would be authorized under 18.130.075]
(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 160 hours supervised practice experience.
   
   (ii) For formal or academic training programs two academic quarters with thirty credit hours each and includes one-hundred and sixty supervised practice experience.
   
   (iii) On-the-Job Training of at least five-hundred and 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) A pharmacy technician training program must renew every five years. Any substantive changes to the program or change in program director must be reported to the commission within thirty calendar days.

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 WAC 246-945-290, 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 state, 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 state with duties that are substantially equivalent to a pharmacy technician in Washington state, the pharmacy technician shall:
   (a) Submit documentation of proof of active practice from another state verification of current active pharmacy practice in another U.S. Jurisdiction; and
   (b) Meet the requirements of chapter 246-12 WAC, Part 2.

WAC 246-945-220 Pharmacy Technician – Continuing Education

(1) As part of the process to renew a pharmacist license, a pharmacist shall complete continuing pharmacy education (CPE) in compliance with this section
(2) A pharmacy technician shall complete twenty CPE 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.

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 WAC 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 a fee in accordance with WAC 246-945-290. 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. Remodels include any physical or functional changes, additions, or modifications to an existing pharmacy or a portion of an existing pharmacy.

(b) Submit a new application on forms provided by the Commission and pay the original license fee in accordance with WAC 246-945-290 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 WAC 246-945-290 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 246-945-005, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with WAC 246-945-290.

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

**WAC 246-945-232 Pharmacy Licensing**
The commission shall issue a pharmacy license to an applicant that:
(1) Is in compliance WAC 246-945-230;
(2) Has a designated responsible pharmacy manager; and
(3) If a pharmacy is new or remodeled the applicant has provided to the commission evidence of being built or remodeled in accordance with all building, health and fire codes required for the particular area.

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 pharmacist 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.

WAC 246-945-235 Non-Resident Pharmacy License

In addition to the requirements in RCW 18.64.360, the commission shall issue a non-resident 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 state in which they are located, and
(4) Has provided to the commission proof that its resident license is in good standing.

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.

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. § 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 WAC 246-945-246(2) 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 state 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 states.

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

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

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.

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) Non-controlled 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;
   (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.

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.

WAC 246-945-253 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 registration 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.
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 chapter 69.50 RCW and chapter 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 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.

(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.

Subpart E – Credentialing Fees

WAC 246-945-290 & 246-945-291

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.

WAC 246-945-310 Responsible Pharmacy Manager

(1) 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. (2) A person may neither be designated nor function as a responsible pharmacy manager for more than three pharmacies concurrently. This limitation does not apply to health care entities licensed under RCW 18.64.450.
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.
   (b) Count, pour, and label for individual prescriptions.

WAC 246-945-320 Non Delegable Tasks

(1) A pharmacist shall not delegate the following:
   (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 and interns 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 modification 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.

WAC 246-945-325 Patient Counseling

(1) The pharmacist shall offer to counsel:
(a) Upon the initial fill of an original prescription.
(b) When the pharmacist using their professional judgement 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.

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 non-controlled legend drug one time in a six-month period when the prescriber is not available for authorization under the following conditions:

(a) The pharmacist communicates the renewal to the prescriber within one business day.
(b) The amount dispensed is the quantity on the most recent fill or a thirty-day supply, whichever is less,

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;
(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, whether from the prescription container, the patient's prescriber or from the pharmacy records;
(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;

Commented [GCO(38): Alternative language for discussion: a seventy two hour supply or the smallest available package size

Commented [GCO(39): New from current WAC, added based on WSPA suggestion.
(c) Mark the face of the prescription as an "emergency" prescription.

(3) Nothing in this rule modifies insurers' requirements for coverage and payment for prescribed medications.

WAC 246-945-335 Prescription Modification

(1) A pharmacist may modify the quantity, dosage, dosage form, or direction of use with prescriber’s authorization and documentation of medication dispensed if it meets the intent of the prescriber.

(2) A pharmacist may complete missing information, such as prescriber’s registration number (for CS), patient address, patient telephone, and allergies without prescriber authorization, on a prescription if there is sufficient evidence to support the change.

(3) A new prescription is required to change a patient’s name, and prescriber’s signature.

(4) A pharmacist may extend 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.

A pharmacist who modifies, completes, or extends a prescription in accordance with these rules must document the modification, supplementation, or extension in the patient’s record.

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 WAC 246-945-340(2)(b) 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 non-pharmacist prescriber listed in RCW 69.41.030 and a pharmacist; and

(c) The formulary is readily retrievable by the pharmacist.

WAC 246-945-345 Prescription Transfers

(1) Upon patient request, a prescription may be transferred within the limits of state and federal law.

(2) Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription.

(3) Pharmacies electronically sharing a secure real-time database are not required to transfer prescription information for dispensing.

(4) Prescriptions must be transferred by electronic means or facsimile, except in emergent situations.

(5) Subsections (1) through (4) 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. 1306.25.

WAC 246-945-350 Collaborative Drug Therapy Agreements
A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location.

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.

A CDTA is only valid for two years from the date of signing.

Any modification of the written guideline or protocol shall be treated as a new CDTA.

WAC 246-945-355 Monitoring of Drug Therapy by Pharmacist

The term "monitoring drug therapy" used in RCW 18.64.011(11) shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. Monitoring of drug therapy shall include, but not be limited to:

1. Collecting and reviewing patient drug use histories;
2. Measuring and reviewing routine patient vital signs;
3. Ordering, administering, and evaluating the results of laboratory tests.

The term "monitoring drug therapy" as used in the definition in "practice of pharmacy" in RCW 18.64.011 shall mean a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen.

Monitoring of drug therapy shall include, but not be limited to:
(a) Performing a patient assessment; and
(b) Ordering, administering, and evaluating the results of laboratory tests.

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.

**WAC 246-945-365 Intent and 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 RCW 18.130 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 (7) calendar days.

(5) A licensee shall report themselves to the commission if they fail to comply with the RCW 18.130.175, the program’s terms and conditions, or any part of this section within seven (7) 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.

(1) The commission will approve recovery, assistance and monitoring programs under RCW 18.130.175 for its credential holders.

(2) When a commission credential holder is referred, or required, to participate in the commission’s approved practitioner, recovery, assistance and monitoring program, the commission may take disciplinary action against the licensee’s credential under RCW 18.130.160 based on any violation by the licensee of the contract between the licensee and the commission’s approved practitioner, recovery, assistance and monitoring program.

The commission will approve practitioner recovery, assistance and monitoring programs, which will participate in the commission’s substance abuse monitoring program under RCW 18.130.175.

**WAC 246-945-370 Sexual Misconduct**

(1) 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.

(2) 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.
Practitioner under this section shall be defined as any person credentialed under RCW 18.64.080, or Chapter 18.64A RCW.

(4) 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 or 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 photographs, materials, other than for legitimate health care purposes.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(9) Patient, client or key party initiation or consent does not excuse or negate the health care practitioner's responsibility.

Part 4 – Operational Standards

Subpart A – Pharmacies, HCE’s and HPAC’s

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.

WAC 246-945-410 Facility Standards
A facility must meet the following minimum requirements:

(1) The facility must 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 must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate 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, to operate safely and, if applicable, to 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.

(5) The facility shall designate a responsible pharmacy manager:

   (1) There must be designated responsible pharmacy manager by the date of opening; and
   (2) Within thirty (30) calendar days of a vacancy.

   (2) Must not allow a vacancy of a designated responsible pharmacy manager to continue for more than thirty 30 calendar days and must be reported in compliance with WAC 246-945-480.

   (3) A person may neither be designated nor function as a responsible pharmacy manager for more than three pharmacies concurrently. This limitation does not apply to health care entities licensed under RCW 18.64.450.

(6) It shall be the responsibility of the facility to create, implement and make available, policies and procedures related to:

   (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering of controlled substances or 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 regulations.
   (c) Adequate security of legend drugs and, including controlled substances.
   (d) Controlling access to controlled substances and 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 drug order before dispensing and delivery shall occur except in emergent medical situations, or if:

   (a) The drug is a subsequent dose from a previously reviewed drug order; and
   (b) The prescriber is in the immediate vicinity and controls the drug dispensing process;
   (c) The 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

Commented [GCO(49): Added to address Storman’s language below

Commented [GCO(50): Move to WAC 246-945-310 as a

Commented [GCO(51]: Moved from Professional Standards

Commented [GCO(52]: Comment: Appears to indicate that a re-review of DURS on a refill would not be necessary. I would caution against this type of language because drug profiles may change, new allergies entered, or new chronic conditions, between fills that would then impact patient safety.
(d) Twenty-four (24) hour pharmacy services are not available, and a pharmacist will review all medication orders added to a patient's profile within six (6) 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 WAC 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, technician, and pharmacy assistant enter the facility's drug storage area under the immediate supervision of a pharmacist, or

(b) A pharmacist authorizes temporary access to the drug storage area to an individual performing a legitimate non-pharmacy 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) 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 WAC 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 non-controlled legend drugs as allowed under federal law.

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 WAC 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).

(2) Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge.

(3) If despite good faith compliance with WAC 246-945-410(4), the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (1)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary pharmacy practice, may include obtaining the drug or device. These alternatives include but are not limited to:

(a) Contact the prescriber to address concerns such as those identified in subsection (1)(a) of this section or to obtain authorization to provide a therapeutically equivalent product;

(b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent;

(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 prescription.

(b) Refuse to return unfilled lawful prescriptions.

(c) Violate a patient's privacy.

(d) Discriminate against patients or their agent in a manner prohibited by state or federal laws.

(e) Intimidate or harass a patient.

(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 restricted drug storage area. Provided 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 addresses by under the policies and procedures developed by the responsible pharmacy manager.
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 patient order or prescription and the order or 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.

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.

(2) The electronic recordkeeping system must be capable of real-time, online retrieval of all information, and have functionality that allows refill data to be readily retrievable and produced upon request.

(3) The electronic recordkeeping system must have audit trail functionality that documents for each prescription the identity of each individual involved at each step of its processing, fulfillment, and dispensing or, alternatively, the identity of the pharmacist responsible for the accuracy of these processes.

(a) Systems must prevent auto-population of user identification information.

(b) Pharmacies that use offsite pharmacy services for product fulfillment or prescription processing must track the identity of each individual involved in each step of the offsite pharmacy services.

(4) 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.

(5) 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.

(6) The pharmacy shall maintain records in accordance with WAC 246-945-020.
Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. § 1311.

HCEs or HPACs that maintain an electronic record system must be done in accordance with (2)-(7) of this section.

**WAC 246-945-418 Paper Recordkeeping Procedure**

If a facility 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.

**WAC 246-945-420 Facility Inventory Requirements**

1. A facility shall conduct its own separate inventory of prescription drugs when it closes.
2. A facility shall conduct its own separate inventory of controlled substances in the following situations:
   a. Within thirty days of becoming designating the responsible pharmacy manager.
   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.
3. A facility shall conduct a separate inventory of prescription drugs after a suspected loss.
4. A pharmacy that stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist onsite shall maintain a perpetual inventory.
5. A pharmacy that stores, dispenses or delivers prescription drugs without pharmacy staff physically on site shall maintain a perpetual inventory.

**WAC 246-945-435 Shared Pharmacy Services**

Pharmacy services may be provided offsite 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. The originating pharmacy shall have written policies and procedures outlining the offsite pharmacy services to be provided by the central fill pharmacy or the offsite pharmacist or pharmacy technician, and the responsibilities and accountabilities of each party.
2. 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 offsite pharmacist or pharmacy technician to the information necessary to perform offsite pharmacy services.
(3) A single prescription may be shared by an originating pharmacy and a central fill pharmacy or offsite 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.

WAC 246-945-430 Pharmacies Storing, Dispensing and Delivering Drugs to Patients Without a Pharmacist On-Site

(1) The following requirements are all in addition to applicable state and federal laws applying to pharmacies.

(2) The pharmacy shall maintain visual surveillance with an adequate number of views 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 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.

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 in compliance with RCW 70.41.480 which must be implemented 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) 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.
(e) Ensure discharge medications are labeled appropriately.
The delivery of a single dose for immediate administration to the patient is not subject to this regulation. Such policies shall allow the practitioner to distribute medications, pursuant to the policies and procedures, as specified in RCW 70.41.480 and the following:

(1) An order of a practitioner authorized to prescribe a drug is presented. Oral or electronically transmitted orders must be verified by the practitioner in writing within seventy-two hours.

(2) The medications distributed as discharge medications must be stored in compliance with the laws concerning security and access. They must be stored in or near the emergency department in such a manner as to preclude the necessity for entry into the pharmacy when pharmacy services are not available.

WAC 246-945-440 Administration of Patient Owned Medications
(1) Facilities shall develop written policies and procedures for the administration of patient owned medications.

(2) Patient owned medications shall be administered only when there is a written order by a practitioner. Prior to use, such medications shall be identified and examined by the pharmacist to ensure acceptable quality for use in the facility.

(3) Patient owned medications which are not used during the patient's admittance to the facility shall be packaged and sealed, stored in the facility's locked drug storage area until discharge or given to the patient's family.

(4) Return of patient owned medications may be prohibited due to possible jeopardy of the patient's health. If medications are not returned, then the health care practitioner shall document the reason in the patient's health record and shall document proper disposal.

(5) Written procedures shall be developed for the disposal of unreturned patient owned medications.

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, co-investigator(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.

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.
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.

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 medication administration safely; 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.

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 supervising supplying pharmacy.

(b) The supervising 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, individuals credentialed by the department under title 18 RCW and within their scope, except 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.

(2) For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.

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.

WAC 246-945-480 Facility Reporting Requirements

Commented [GCO(69)]: The current interpretation has been that this should be placed in a facility that is able to possess/store drugs. To be consistent that limitation could be added. Currently this rule would allow a pharmacy to store drugs in an RTF in a designated area outside the pharmacy.

Commented [GCO(70)]: If this section is meant to apply to facilities other than pharmacies, I would recommend making that change in the rule.
(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 (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.

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) Non-controlled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned and reused if product integrity can be assured.

   (b) Those that qualify for return under the provisions of the chapter 69.70 RCW.

(2) A dispensed drug or prescription device may be accepted for return and destruction as follows if:

   (a) The dispensed drug or prescription device that was dispensed in a manner inconsistent with the prescriber’s instructions may be returned for quarantine and destruction purposes only.

   (b) As part of the return is in compliance with the Washington state safe medication return program laws and rules and consistent with chapter 69.48 RCW and chapter 246-480 WAC.

   (c) The return and destruction is in compliance with the facility’s waste and destruction policies and procedures.

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.

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 accepted professional standards set forth in the United States Pharmacopeia USP <800> and <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 accepted professional standards set forth in the United States Pharmacopeia USP <800> and <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 non-immediate use; and
(h) specific concentration of radioactivity;
(i) the patient name/identifier, and number of dosage units dispensed, for all therapeutic and blood-products,
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; and
(g) activity dispensed with units (millicuries or microcuries) at calibration date and time;
(h) the patient name/identifier for all therapeutic and blood-products

The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

A nuclear pharmacy may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

The nuclear pharmacy shall have readily available the current applicable state laws and regulations of the commission and state radiation control agency.

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.

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.

WAC 246-945-495 Continuous Quality Assurance Program

(1) Each facility shall create or participate in a quality assurance program to detect, identify, and prevent medication errors. The quality assurance program shall include necessary documentation, internal reporting, and assessment of prescription errors to determine the cause and an appropriate response.

(2) The primary purpose of the quality assurance program shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors such as system or process failures.

Commented [GCO(72): Comment from OS: There is significant legal concern of whether pharmacies may receive CQIPs based on RCW 43.70.510 because the statute indicates licenses issued by the secretary and the commission issues these certificates. Suggest getting legal advice from your AAG who works in conjunction with AAG Eric Sonju on this issue. Thanks!}
(3) Each facility shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors, as well as communicate those findings to all pharmacy personnel.

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 animal control agency, humane society, or department of fish and wildlife chemical capture program shall notify the commission within 10 (ten) calendar days of a change in the designated person.

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 designated person; 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 or completed through a program recognized by the national veterinarian association. 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.
WAC 246-960-505 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;
(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.

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) Any approved drug used by the registered department of fish and wildlife chemical capture programs shall be marked “for veterinary use only.”

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 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 subsections (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 designated person for investigation.

(5) The registered entity shall report any unresolved discrepancies in writing to the commission within seven (7) 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 six months. The physical inventory must be reconciled with the logbook or electronic record.

(7) The designated responsible person or designee shall destroy or waste non-controlled 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 non-controlled 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.

WAC 246-945-515 Human 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-
1503(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-
1503(3);
The approved drugs are stored in a locked metal box securely attached to a vehicle;
(c) A drug inventory is completed at the beginning and at the end of each shift and recorded in a log book 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.

**Subpart C – Drug Distributors**

**WAC 246-945-550 Drug Manufacturers – Minimum Standards**

(1) Manufacturers shall comply with the applicable requirements in 21 CFR, Part 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 CFR, 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. § 353b(d)(4)(A), shall also comply with the following:
   (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.

(3) Virtual manufacturers shall ensure its own drugs are manufactured in compliance with this section.

**WAC 246-945-555 Wholesaler Standards Applicability – Minimum Standards - Scope**

(1) WAC 246-945-560 through WAC 246-945-600 establish the minimum standards for facilities licensed as wholesalers, their officers, designated representative, 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 WAC 246-945-600.

**WAC 246-945-560 Wholesaler – Facility Standards Facility Requirements**

(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.

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 SE, 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 non-controlled 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.

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.

**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.

   (a) The records must include at least:

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

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

   (iii) 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.

**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.

**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 to the Commission 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 (15) 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;

(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 non-controlled prescriptions and overall sales;

(iii) Orders for controlled substances or drugs of concern from other wholesalers;

US 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 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 fifty business (50) 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 of an emergent need for a specific patient.

(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); and

(e) A detailed explanation of why the wholesaler identified the customer as a possible diversion risk.

(6) Such reports shall be submitted within thirty (30) days of refusal, cessation, or identification by wholesaler.

(7) All licensed wholesalers shall submit all reports to the Commission in a DEA ARCOS format.

WAC 246-945-590 Wholesaler – Policies and Procedures

Wholesalers shall establish, maintain, and adhere to written policies and procedures, 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 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:

(9) The wholesaler’s suspicious order monitoring system;
(10) The process to collect all relevant information on customers in accordance with WAC 246-960-330; and
(11) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.
(12) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

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 labelling 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 licensed 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;
(12) The distribution or wholesale distribution of a drug that was previously dispensed by a pharmacy or distributed by a practitioner.

WAC 246-945-600 Salvaging and Reprocessing
Wholesalers shall be subject to the provisions of any applicable Federal, State, or local 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.