**General Provisions**

**WAC 246-945-010 Definitions**

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise. In addition to RCW 18.64.011

1. “ACPE” means Accreditation Council for Pharmacy Education.
2. “Animal Control Agency” as defined in chapter 69.50 RCW
3. "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.
4. “Chemical Capture Program” as defined in chapter 69.50 RCW.
5. “Controlled Substances” means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or commission rules, but does not include industrial hemp as defined in RCW [15.120.010](http://app.leg.wa.gov/RCW/default.aspx?cite=15.120.010).
6. “Commission” means the Pharmacy Quality Assurance Commission.
7. “Commission approved programs" means pharmacy technician education and training programs which has been reviewed and approved by the commission.
8. “CPE” means continuing pharmacy education accredited by the Accreditation Council for Pharmacy Education (ACPE).
9. “Credential” means a license, certification, or registration 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.
10. “DEA” means the United States Federal Drug Enforcement Administration.
11. Delegable Tasks - Delegable tasks are those tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy technician's own judgment and discretion, and which do not require the pharmacy technician to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy
12. “Department” means the Washington State Department of Health.
13. Direct supervision - with respect to the supervision of the pharmacy technician or pharmacy technician trainee, that a licensed pharmacist is:

(a) Physically present at the same pharmacy as the pharmacy technician or pharmacy technician trainee and in the general vicinity of the pharmacy technician or pharmacy technician trainee;

(b) Readily available to answer questions of the pharmacy technician or pharmacy technician trainee;

(c) Making appropriate in-process and end-process verifications of the activities of the pharmacy technician or pharmacy technician trainee; and

(d) Fully responsible for the practice of the pharmacy technician or pharmacy technician trainee."

1. Drug Advertising – means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs
2. “Drug standard and information sources” means industry recognized reference and resources (e.g. Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations)
3. “Enrolled” refers to 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.
4. “FDA” – United States Federal Food and Drug Administration
5. “Full-line Wholesaler” means a drug wholesale distributor that sells nonprescription and prescription drugs.
6. “FPGEC” means Foreign Pharmacy Graduate Examination Committee.
7. “FPGEE” means Foreign Pharmacy Graduate Equivalency Examination
8. "Hospital" means any institution licensed pursuant to chapters 70.41 or 71.12 RCW or designated pursuant to RCW 72.23.020.
9. "Hospital pharmacy" means that portion of a hospital which is engaged in the manufacture, production, preparation, dispensing, sale, and/or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases; and which is licensed by the state board of pharmacy pursuant to the Washington State Pharmacy Practice Act, chapter 18.64 RCW.
10. "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.
11. “Inoperable” refers to 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.
12. "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.
13. "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential habilitation center, or a local, state, or federal correction facility.
14. “Investigational drug" means any article which has not been approved for use in the United States, but for which an investigational drug application (IND) has been approved by the FDA.
15. “MPJE” the Multistate Pharmacy Jurisprudence Examination for Washington.
16. “NABP” means the National Association of Boards of Pharmacy.
17. “NDC” means National Drug Code
18. "Nuclear pharmacy" is a pharmacy providing radiopharmaceutical services.
19. "Nuclear pharmacist" means a licensed pharmacist who has submitted evidence to the commission that they meet the requirements of WAC 246-903-030 of these regulations regarding training, education, and experience, and who has received notification by letter from the commission that, based on the evidence submitted, he or she is recognized by the commission as qualified to provide radiopharmaceutical services.
20. Offsite - Pharmacies that are not located in the facilities they serve and whose primary purpose is to provide services to patients
21. “Over-the-counter drugs” means “nonlegend" or "nonprescription" drugs, any drugs which may be lawfully sold without a prescription.
22. Partial Fill –a part of a prescription filled that is of a quantity less than the entire prescription
23. Pharmaceutical facility - means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this state.
24. "Plan of correction" is a proposal devised by the applicant or pharmacy that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.
25. “Precursor Drugs” as defined in chapter 69.43 RCW.
26. “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 law (including federal 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.
27. "Protocol" means a written set of guidelines.
28. "Radiopharmaceutical service" shall mean, but shall not be limited to, the preparing, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.
29. A "radiopharmaceutical" is any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any 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’.
30. "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.
31. Readily Retrievable – describes 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.
32. “Reciprocity or 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-LTPTM)
33. Responsible Pharmacy Manager - The pharmacy, organized as a separate department or service, shall be directed by a licensed pharmacist appropriately qualified by education, training, and experience to manage a hospital pharmacy. The patient care and management responsibilities of the responsible pharmacy manager shall be clearly delineated in writing and shall be in accordance with currently accepted principles of management, safety, adequate patient care and treatment. The responsibilities shall include the establishment and maintenance of policies and procedures, ongoing monitoring and evaluation of pharmaceutical service, use and control of drugs, and participation in relevant planning, policy and decision-making activities. Hospitals which do not require, or are unable to obtain the services of a fulltime responsible pharmacy manager shall be held responsible for the principles contained herein and shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services. Where the responsible pharmacy manager is not employed fulltime, then the hospital shall establish an ongoing arrangement in writing with an appropriately qualified pharmacist to provide the services described herein.
34. “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.
35. “Secretary” means the secretary of health.
36. "Self-administration of drugs" means that a patient administers or takes his/her own drugs from properly labeled containers: Provided, That the facility maintains the responsibility for seeing that the drugs are used correctly and that the patient is responding appropriately
37. “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.
38. “VAWD” means Verified-Accredited Wholesale Distributors® accreditation program for facilities engaged in the act of wholesale drug distribution.
39. “VIPP” means Verified Internet Pharmacy Practice Sites accreditation program for pharmacy services offered on the internet.

**PART 1 PQAC OPERATIONS**

**WAC 246-945-020 Administrative Proceedings and Appeals**

1. The commission adopts the model procedural rules for administrative proceedings as adopted by the department of health, 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 as adopted by the department, including subsequent amendments under chapter 246-12 WAC, unless otherwise addressed in rules adopted by the commission.

**WAC 246-945-030 Commission Inspections and Investigations**

1. Records Subject to Commission Inspection. Records created, maintained, or retained by commission credential holders in compliance with statutes or rules enforced by the commission must be made available for inspection upon request by commission inspectors or authorized designee. It is unlawful to refuse to permit or to obstruct a commission inspection.
2. Initial Inspections. Prior to the commencement of business, as applicable, and upon presentation of appropriate identification, credential holder and licensees must 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 pharmacy is subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy.
	1. Statement of Deficiency.
		1. At the end of the inspection, the commission, or its designee, will conduct an exit meeting with the responsible pharmacy manager or designee(s), addressing unresolved deficiencies identified during the inspection.
		2. The commission, or its designee, shall provide a written statement of deficiency to the pharmacy ten (10) business days of the exit meeting.
		3. 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.
	2. Plan of correction. A pharmacy must submit a plan of correction to the commission, or its designee, addressing each identified unresolved deficiency within ten (10) business days of receipt of a statement of deficiency.
		1. The commission, or its designee, must notify the pharmacy within 14 calendar days, whether or not a submitted plan of correction adequately addresses the unresolved deficiencies identified in the inspection report.
		2. 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.
	3. Pharmacies 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, is required to conduct an annual self-inspection of the pharmacy on the responsible pharmacy manager self-inspection worksheet(s) provided by the commission. The self-inspection must be completed within the month of March each year.
	1. The responsible pharmacy manager must sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion.
	2. When a change in responsible pharmacy manager occurs, the new responsible pharmacy manager, or designee, shall conduct a self-inspection on the responsible pharmacy manager self-inspection worksheet(s). The new responsible pharmacy manager must sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, and maintain completed worksheets for two years from the date of completion.
5. Investigations. Credential holders must 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.
6. Inspection Informal Dispute Process
	1. A facility may dispute:
		1. Any or all deficiencies included on a statement of deficiencies issued by the Commission;
		2. The rejection of the first submitted plan of correction.
	2. A facility must submit a dispute under this subsection to the Commission in writing, including by electronic means. The dispute must be in detail and include any supporting documentation for commission consideration.
	3. The Commission may review and consider a second rejection of a plan of correction.
	4. The Commission shall consider any dispute submitted within thirty (30) days of receipt of the submitted dispute, and notify the facility of its determination.

**Part 2 LEGEND DRUGS & CONTROLLED SUBSTANCES**

**WAC 246-945-040 Identification of legend drugs for purposes of chapter** [**69.41**](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41) **RCW.**

1. In accordance with chapter [69.41](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41) RCW, the commission finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect The methods of their use and the collateral safeguards necessary for their use indicate that they are only safe for use under the supervision of a practitioner.
2. For the purposes of chapter [69.41](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41) RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2009 edition of the *Drug Topics Red Book*. Copies of the list of legend drugs as contained in the *Drug Topics Red Book* are available for public inspection at the headquarters office of the Pharmacy Quality Assurance Commission, 111 Israel Road SE, Tumwater, WA 98501. To obtain copies of this list from the department, interested persons must submit a written request, indicating which format they wish to receive, and payment of the actual cost of the text or CD, including shipping and handling charges from the publisher. Requestors may also contact the publisher directly to obtain copies. The department takes no responsibility for periodic updates or online access. Arrangements for periodic updates or online access must be made directly with the publisher.
3. There may be changes in the marketing status of drugs after the publication of the above reference. The commission may grant authority for the over the counter distribution of certain drugs that had been designated as legend drugs after the manufacturer or distributor submits an application. These determinations will be made after public hearing and will be published as an amendment to this chapter.

**WAC 246-945-060 Drug sample prohibitions.**

1. The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby prohibited.
2. This shall not apply to any 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.

**WAC 246-945-070 Ephedrine prescription restrictions.**

1. The commission, pursuant to RCW [69.41.075](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41.075), hereby 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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41.030).
2. The following products containing ephedrine or its salts in the amount of 25 mg. or less per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts are exempt from subsection (1) of this section:

|  |  |  |
| --- | --- | --- |
|   | TRADE NAME | EPHEDRINE CONTENT |
| 1. | AMESAC capsule (Russ) | 25 mg. ephedrine HCL |
| 2. | AZMA AID tablet(Various, eg Purepac) | 24 mg. ephedrine HCL |
| 3. | BRONC-EASE PLUS(Natur-Pharma) | 25 mg. ephedrine HCL |
| 4. | BRONCHODILATORAND EXPECTORANT(PDK Labs) | 25 mg. ephedrine HCL |
| 5. | BRONITIN tablet(Whitehall) | 24 mg. ephedrine HCL |
| 6. | BRONKAID tablet(Breon) | 24 mg. ephedrine sulfate |
| 7. | BRONKOLIXER(Sterling Winthrop) | 12 mg. ephedrine |
| 8. | BRONKOTABS tablet(Breon) | 24 mg. ephedrine sulfate |
| 9. | EFEDRON nasal jelly(Hyrex) | 0.6% ephedrine HCL in 20 g. |
| 10. | MINI THINS asthma relief (BDI Pharmaceuticals) | 25 mg. ephedrine |
| 11. | PAZO HEMORRHOIDsuppositor(Bristol-Meyers) | 3.86 mg. ephedrine sulfate |
| 12. | PAZO HEMORRHOIDointment(Bristol-Meyers) | 0.2% ephedrine sulfate |
| 13. | PRIMATENE tablet(Whitehall) | 24 mg. ephedrine HCL |
| 14. | PRIMATENE M tablet(Whitehall) | 24 mg. ephedrine HCL |
| 15. | PRIMATENE P tablet(Whitehall) | 24 mg. ephedrine HCL |
| 16. | QUELIDRINE(Abbott) | 5 mg. ephedrine HCL |
| 17. | TEDRAL tablet (Parke-Davis) | 24 mg. ephedrine HCL |
| 18. | THEODRINE tablet(Rugby) | 25 mg. ephedrine HCL |
| 19. | VATRONOL nose drops(Vicks Health Care) | 0.5% ephedrine sulfate |

1. 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.
2. 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.
3. 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:
	1. Provides the commission with the formulation of any such product;
	2. 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
	3. Receives the commission's approval to market such product.

**WAC 246-945-080 Regulated steroids.**

The commission finds that the following drugs shall be classified as steroids for the purposes of RCW [69.41.310](http://app.leg.wa.gov/RCW/default.aspx?cite=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 from the attached list:

1. Anabolicum
2. Anadrol
3. Anatrofin
4. Anavar
5. Androxon
6. Andriol
7. Android
8. bolandiol
9. bolasterone
10. boldenone
11. boldenone undecylenate
12. bolenol
13. Bolfortan
14. bolmantalate
15. Cheque
16. chlorotestosterone
17. clostebol
18. Deca Durabolin
19. dehydrochlormethyl-testosterone
20. Delatestyl
21. Dianabol
22. Dihydrolone

**WAC 246-945-090 Theophylline prescription restrictions.**

The commission, pursuant to RCW [69.41.075](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41.075), hereby 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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41.030). Provided, products containing 130 mg or less of theophylline per solid dosage unit or 130 mg or less per 5 ml of liquid forms, shall not be considered a legend drug and where the product contains other recognized therapeutic ingredients, may be sold or distributed without a prescription. Products with theophylline as the only active ingredient are identified as legend drugs.

**WAC 246-945-100 Availability.**

Amygdalin (laetrile) shall be available in intrastate commerce to the citizens of the state of Washington in accordance with all applicable state laws and regulations. Amygdalin (laetrile) imported into the state of Washington shall be imported in conformity with federal regulations and/or court decisions.

**WAC 246-945-110 Identity.**

Certification of batches of amygdalin (laetrile) shall be made under the direction of the commission, with the costs for required testing, including purity and potency, to be borne by the manufacturer and/or wholesale distributor. The manufacturer and/or wholesale distributor shall be held totally responsible for the quality of the drug product, in accordance with RCW [18.64.270](http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.270).

**WAC 246-945-120** **Uniform Controlled Substances 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 chapter 246-945 WAC should be resolved in favor of chapter 246-945 WAC. 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 and in accordance with [Recordkeeping Section of new draft]. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:
	1. 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;
	2. 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;
	3. 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;
	4. 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. Said record 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.
4. Records for Schedule II drugs must be maintained separately from all other records. The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable from the business records of the registrant.
5. A federal order form is required for each distribution of a Schedule I or II controlled substance. These forms and other records must be kept and made readily available to the commission or commission designee.
6. Dispensers must possess a valid prescription for a Schedule II drug prior to dispensing that drug, unless an “emergency” exists. 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 physician to provide a written or electronic prescription for the drug at that time. If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven-day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.
7. A prescription for a substance included in Schedule II may not be refilled.
8. A prescription for a substance included in Schedule II may not be filled more than six months after the date the prescription was issued.
9. Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule III, IV, or V, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written, oral, or electronically communicated prescription of a practitioner. Any oral prescription must be promptly reduced to writing. The prescription for a substance included in Schedule III, IV, or V may not be filled or refilled more than six months after the date issued by the practitioner or be refilled more than five times, unless the practitioner issues a new prescription.

**WAC 246-945-125** **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 246-945-130** **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 246-945-140** **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 excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

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

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

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

(d) Dextrorphan;

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

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

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

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

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

(j) Propheptazine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**WAC 246-945-145** **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 decocainized coca leaves or extractions which do not contain cocaine or ecgonine; or [123I]ioflupane.

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

(3) Hallucinogenic substances.

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

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

(4) Immediate precursors. Unless specifically excepted 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 246-945-150** **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 excepted 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 246-945-160** **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 246-887-100 and Schedule II under RCW 69.50.206 and WAC 246-887-140, 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 excepted 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);

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

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

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

Table A

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

**WAC 246-945-165** **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 246-887-160, 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 excepted 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 excepted 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 excepted 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 246-945-170 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 246-887-170 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule V.

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

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

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

(3) 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 246-945-180** **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 246-887-150.

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

(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 Federal Drug Enforcement Administration.

**WAC 246-945-200 Precursor Substance Control**

1. For the purpose of this chapter a precursor substance is any of the following substances or their salts or isomers:
	1. Gamma-butyrolactone (GBL);
	2. Hydriodic acid;
2. Provided; that this definition shall 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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.04) or [69.41](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41) RCW.
3. Registrants should be aware that precursor substances in subsection (1) (a) and (b) of this section are also regulated as schedule II immediate precursors pursuant to WAC 246-xxx-150 and all applicable rules and laws governing the distribution of schedule II controlled substances must also be complied with.

**246-945-210 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-XXX-120 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:
	1. Name of substance;
	2. Quantity received;
	3. Date received;
	4. Name and address of firm or person receiving substance; and
	5. Name and address of the source selling, transferring, or furnishing the substance.
3. The report shall be on a form approved by the commission: Provided, That 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 set forth in subsection (2) of this section. Under this option purchase price information appearing on the document can be deleted.

**246-945-220 Monthly reporting option.**

1. Permit holders who regularly transfer the same precursor substance to the same recipient can 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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.43.010)(5), are met and will notify the permit holder of its decision and the reporting format that will be authorized.
2. Permit holders may also petition the commission to accept the monthly report on a computer-generated basis. The report can be furnished in hard copy, on commission-approved data storage methods or by computer interface with a commission-operated computer. The permit holder will be 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 can be rescinded at the commission's discretion and with thirty (30) day’s notice.

**246-945-230 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. For the purpose of this rule, a regulated product is defined as a product specified in RCW [69.43.010](http://app.leg.wa.gov/RCW/default.aspx?cite=69.43.010)(1) or WAC 246-XXX-120.
2. For the purposes of this rule, a "suspicious transaction" is defined as any sale or transfer that meets any of the following criteria:
	1. 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](http://app.leg.wa.gov/RCW/default.aspx?cite=69.50) RCW, based on such factors as:
		1. The amount of the substance involved;
		2. The method of payment;
		3. The method of delivery; or
		4. Any past dealings with any participant in the transaction.
	2. Any individual sale or transfer of a regulated product that exceeds ten (10) 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.)
	3. Any order which contains regulated products and has no additional nonprescription drugs is considered a suspicious transaction.
3. Pharmacy Reporting Requirements
	1. Significant losses or disappearances of controlled substances and the facts surrounding the discrepancy shall be reported to the commission, the DEA, the executive officer of the hospital and other appropriate authorities.

**246-945-240 Requirements for the sale of restricted product.**

Unless exempted in RCW [69.43.110](http://app.leg.wa.gov/RCW/default.aspx?cite=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-XXX-165 in the record of transaction before completing the sale.

**WAC 246-945-245 Record of sales—Electronic methamphetamine precursor tracking.**

1. Unless granted an exemption under RCW [69.43.110](http://app.leg.wa.gov/RCW/default.aspx?cite=69.43.110) upon the sale or attempted sale of a restricted product, each retailer must enter and electronically transmit the following information to the methamphetamine precursor tracking system prior to completion of the transaction:
	1. Sale transaction information including:
2. Date and time of the intended purchase;
3. Product description;
4. Quantity of product to be sold including:
	1. Total grams of restricted product per box;
	2. Number of boxes per transaction; and
	3. Purchaser's information including:
5. Full name as it appears on the acceptable identification;
6. Date of birth;
7. 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;
8. 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
9. 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.
	1. The full name or initials of the individual conducting the transaction.
	2. Other information as required by the methamphetamine precursor tracking system database.
10. 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.

**246-945-250 Acceptable forms of photo 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.

**246-945-260 Maintenance of and access to retail sales records of restricted products.**

1. The retail sales records required under WAC 246-XXX-165 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:
	1. Only authorized employees have access to the databases;
	2. Each employee use his or her unique password or access code to access the databases;
	3. Each employee adheres to all state and federal laws regarding confidentiality; and
	4. 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.

Part 3 Prescription & Labeling

**WAC 246-945-300 Prescription and Chart Order: Minimum Requirements.**

1. All prescription drug orders must comply with applicable requirements of federal law and, must include at least the following:
	1. The patient’s or authorized entity’s name and:
		1. If for a controlled substance, the patient’s full name and address; and
		2. If for an animal, the species.
	2. The date issued.
	3. The drug name, strength, quantity and, if for a controlled substance, the dosage form.
	4. The directions for use.
	5. The name, the address, and DEA registration number of the prescriber if a controlled substance.
	6. If paper:
		1. If written in Washington State complies with RCW 18.64.500 ;
		2. Prescriber’s name is pre-printed, stamped or hand-printed;
		3. Wet signature of the prescriber or, if statutorily allowed, the prescriber’s agent’s signature; and
		4. If electronic, the prescriber’s electronic signature.
2. A chart order must meet the requirements of RCW 18.64.550.

**WAC 246-945-310 Prescriptions: Validity.**

1. Prescriptions for legend drugs are valid for one (1) year after the date issued by the prescriber and valid for six months for controlled substances.

(2) Prior to fulfillment or dispensing a prescription drug order, a pharmacist must verify its validity.

* 1. A prescription drug order is invalid if, at the time of presentation, it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it.
	2. A prescription drug order is invalid after its expiration date as follows:
1. A prescription drug order for a Schedule II controlled substance must not be filled or dispensed more than six months after its date of issue.
2. A prescription drug order for a controlled substance listed in Schedules III, IV or V must not be filled or refilled more than six (6) months after its date of issue.
3. A prescription drug order for a non-controlled drug must not be filled or refilled more than twelve (12) months after its date of issue.

**WAC 246-945-315 Prescription container labeling.**

To every prescription container, there shall be fixed a label or labels bearing the following information:

1. All information as required by RCW [18.64.246](http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.246), provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:
	1. The nature of the drug;
	2. The container in which it was packaged by the manufacturer and the expiration date thereon;
	3. The characteristics of the patient's container, if the drug is repackaged for dispensing;
	4. The expected conditions to which the drug may be exposed;
	5. The expected length of time of the course of therapy; and
	6. Any other relevant factors.
2. In additional to (1) The dispenser shall place on the label of a multiple unit container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.
3. The quantity of drug dispensed, for example the volume or number of dosage units.
4. 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."
5. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-XXX-045 (Professional Standards).

**WAC 246-945-320 Labeling: Ambulatory Prescriptions.**

All labeling requirements of RCW 18.64.246 must be followed, unless otherwise directed by these rules, a prescription drug must be dispensed in a USP compliant container that bears the following information:

1. Patient’s Name.
2. If an animal, the name and species of the patient; or
3. If a facility or other entity is authorized to possess a legend drug in accordance with RCW 70.54.440, the name of the facility or entity.
4. The quantity of item dispensed.
5. Cautionary information as necessary or deemed appropriate for proper use and patient safety.
6. The number of refills remaining, if any, or the last date through which the prescription is refillable.
7. A warning sufficient to convey that state or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed, except when dispensing to an animal, when a warning sufficient to convey “for veterinary use only” may be utilized.

**WAC 246-945-330 Labeling: Chart Orders.**

All labeling requirements of RCW 18.64.246 must be followed, except if dispensed in unit dose packaging, a drug dispensed for patient use while in a hospital must be dispensed in an appropriate container that bears at least the following information:

(1) The quantity of item dispensed;

(2) Cautionary information as necessary or deemed appropriate for proper use and patient safety

**WAC 246-945-340 Labeling: Compounded Prescription Medication**

A compounded product must comply with all labeling requirements of 18.64.246 and meet the labeling requirements of the USP chapters <795>, <797> and <800>.

**WAC 246-945-350 Labeling: Prepackaged Product.**

Prepackaged drugs must include a label with the following information; drug name, drug strength, expiration date, the manufacturer’s name and lot number and the identity of the pharmacist or provider responsible for the prepackaging. If not maintained in a separate record.

**Part 4 – Unnamed so far**

**WAC 246-945-400 Advertising**

(1) A pharmacy may advertise legend or prescription drug prices provided:

* 1. The advertising complies with all state and federal laws, including regulations of the FDA and the Washington State Consumer Protection Act, chapter [19.86](http://app.leg.wa.gov/RCW/default.aspx?cite=19.86) RCW.
	2. 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.
	3. The drug price advertising shall contain all the following information for all drug products or brand names used in the advertisement:
		1. The proprietary name of the drug product advertised, if any,
		2. The generic name of the drug product advertised, if any,
		3. 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.
		4. The price charged for a specified quantity of the drug product.
1. 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.
2. No person, partnership, corporation, association or agency shall 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 shall not be physically displayed to the public.
3. No pharmacy shall refuse to disclose the at cost price of a prescription drug upon request by a consumer.

**246-945-410** **Home dialysis program—Legend drugs.**

1. Pursuant to RCW [18.64.257](http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.257) and [69.41.032](http://app.leg.wa.gov/RCW/default.aspx?cite=69.41.032), a medicare-approved dialysis center or facility operating a medicare-approved home dialysis program may sell, deliver, possess and/or dispense directly to its home dialysis patients in cases or full shelf package lots, if prescribed by a physician, the following legend drugs:
	1. Sterile heparin, 1000u/ml, in vials;
	2. Sterile potassium chloride, 2mEq/ml, for injection;
	3. Commercially available dialysate; and,
	4. Sterile sodium chloride, 0.9%, for injection in containers of not less than 150ml.

**246-945-420 Pharmacist consultant.**

Home dialysis programs involved in the distribution of legend drugs as permitted by RCW [18.64.257](http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.257) and [69.41.032](http://app.leg.wa.gov/RCW/default.aspx?cite=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.

**246-945-430 Records.**

1. A record of shipment shall be attached to the prescriber's order and shall include: The name of the patient, strengths, and quantities of drugs; the manufacturers' names; date of shipment; names of persons who selected, assembled and packaged for shipment; and, the name of the pharmacist or designated individual responsible for the distribution.
2. Prescription and drug distribution records shall be maintained in accordance with commission record retention requirements.

**246-945-450 Quality assurance.**

Home dialysis programs involved in the distribution of legend drugs as permitted by RCW [18.64.257](http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.257) and [69.41.032](http://app.leg.wa.gov/RCW/default.aspx?cite=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.