## General Provisions

### 246-XXX-030 Definitions

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "ACPE" means Accreditation Council for Pharmacy Education.

(2) "Animal Control Agency" as defined in chapter 69.50 RCW

~~(2)~~(3) "Aseptic Techniques refers to a specific set of practices performed in certain clinical settings to prevent the spread of pathogens and create a sterile environment.

~~(3)~~(4)"Chemical Capture Program" as defined in chapter 69.50 RCW.

~~(4)~~(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.

~~(5)~~(6)"Commission" means the Pharmacy Quality Assurance Commission.

~~(6)~~(7)"Commission approved programs" means pharmacy technician education and training programs which has been reviewed and approved by the c~~C~~ommission office.

~~(7)~~(8)"Department" means the Washington State Department of Health.

~~(8)~~(9)"CPE" means continuing pharmacy education accredited by the Accreditation Council for Pharmacy Education (ACPE).

~~(9)~~(10) "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)~~(11)"DEA" means the federal Drug Enforcement Administration.

~~(11)~~(12)"Drug standard and information sources" means industry recognized reference and resources (e.g. Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations)

~~(12)~~(13) "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.

~~(13)~~(14)"Full-line Wholesaler" means a drug wholesale distributor that sells nonprescription and prescription drugs.

~~(14)~~(15)"FPGEC" means Foreign Pharmacy Graduate Examination Committee.

~~(15)~~(16)"FPGEE" means Foreign Pharmacy Graduate Equivalency Examination

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~~(16)~~(17) “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.

~~(17)~~(18)“Health Care Entity” as defined in chapter 18.64 RCW.

~~(18)~~(19)“Manufacturer” as defined in chapter 18.64 RCW.

~~(19)~~(20)“MPJE” the Multistate Pharmacy Jurisprudence Examination for Washington.

~~(20)~~(21)“NABP” means the National Association of Boards of Pharmacy.

~~(21)~~(22)“Over-the-counter drugs” means “nonlegend" or "nonprescription" drugs ~~means,~~ any drugs which may be lawfully sold without a prescription.

~~(22)~~(23)“Pharmacy” as defined in chapter 18.64 RCW

~~(23)~~(24)“Pharmacy Assistant” as defined in chapter 18.64A RCW.

~~(24)~~(25)“Pharmacy Intern” as defined in chapter 18.64 RCW.

~~(25)~~(26)“Pharmacy Technician” as defined in chapter 18.64A RCW.

(27) “Pharmacist” as defined in chapter 18.64 RCW.

~~(26)~~(28) "Plan of correction" is a proposal devised by the applicant or pharmacy that specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

~~(27)~~(29)“Precursor Drugs” as defined in chapter 69.43 RCW.

~~(28)~~(30)“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-LTP™)

~~(29)~~(31)“Reverse Distributor” means a pharmaceutical wholesaler that ~~received~~ receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

~~(30)~~(32) “Secretary” means the secretary of health.

~~(31)~~(33)“Shopkeeper” as defined in chapter 18.64 RCW

~~(32)~~(34)“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.

~~(33)~~(35)“VAWD” means Verified-Accredited Wholesale Distributors® accreditation program for facilities engaged in the act of wholesale drug distribution.

(36) "VIPP" means Verified Internet Pharmacy Practice Sites accreditation program for pharmacy services offered on the internet.

(37) Offsite

(38) Dispensing

(39) "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.

(40) "Authenticated" or "authentication" means authorization of a written entry in a record by means of a signature which shall include, minimally, first initial, last name, and title.

(41) "Hospital" means any institution licensed pursuant to chapters 70.41 or 71.12 RCW or designated pursuant to RCW 72.23.020.

(42) ("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.

(43) "Immediate supervision" means visual and/or physical proximity that insure adequate safety and controls.

(44) "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.

(45) "Protocol" means a written set of guidelines.

~~(34)~~(46) "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

**Commented [GCO(2]:** Definition referenced in Operational Standards

**Commented [GCO(3]:** Definition reference in Operational Standards

**Commented [GCO(4]:** Added from Hospital Standards

## Part 1 PQAC Operations

### WAC 246-XXX-010 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.

**Commented [BD(5]:** AAG request to split the section into two to separate the appeal process and the application process.

**WAC 246-xxx-040 Practice of Pharmacy – General Approach**

A pharmacist's scope of practice is defined in RCW 18.64.011(28). To evaluate competence of an individual credential holder should determine:

(1) Express Prohibition. The act is expressly prohibited by:
  (a) The Washington state pharmacy practice act Chapter 18.64 RCW;
  (b) The Uniform Controlled Substance act Chapter 69.50 RCW;
  (c) The rules of the Commission; or
  (d) Any other applicable state or federal laws, rules or regulations.

(2) Education and Training. The act is consistent with credential holder's education, training or practice experience.

(3) Standard ~~or~~ of Care. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent credential holder with similar education, training and experience.

**WAC 246-xxx-050 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.
  (a) Statement of Deficiency.
    (i) At the end of the inspection, the commission, or its designee, will conduct an exit meeting with the responsible 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 pharmacy 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 pharmacy must submit a plan of correction to the commission, or its designee, addressing each identified unresolved deficiency within 10 business days of receipt of a statement of deficiency.
    (i) A "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.

**Commented [BD(6]:** Should this be a policy statement on the web?

**Commented [GCO(7]:** Subject?

**Commented [BD(8]:** New rule – implementation and effectiveness of timelines re

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**Commented [WTM(10]:** Definition Section.

(ii) The commission, or its designee, must notify the pharmacy within ten calendar days, whether or not a submitted plan of correction adequately addresses the unresolved deficiencies identified in the inspection report.

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

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

(a) The responsible manager must 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 manager occurs, the new responsible manager, or designee, shall conduct a self-inspection on the responsible manager self-inspection worksheet(s). The new responsible manager must sign and date the self-inspection worksheet(s) within thirty days of becoming responsible 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.

**Commented [WTM(11]:** Are we going to have this stated throughout, or stated once and referred to in other places.

**Commented [WTM(12]:** Question previously was whether this should be stated more clearly, i.e. start date

**WAC 246-XXX-005 Written Interpretations**

The commission may have written statements that pertain to the interpretation of the rules of this chapter. Any such documents are available for public inspection at cost at the Commission office.

## Part 2 Unnamed

**246-xxx-xxx Identification of legend drugs for purposes of chapter 69.41 RCW.**

(1) In accordance with chapter 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 to their use indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 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.

**246-xxx-xxx Introductory trade or stock packages.**

Introductory trade or stock packages may be distributed by registered drug manufacturers to licensed pharmacies under the following conditions:

(1) The package shall be invoiced by the drug manufacturer as a no charge sale.

(2) The product shall be distributed by the manufacturer to the pharmacy by mail or common carrier.

(3) The drug's package shall not be marked as a sample or with any other labeling that is inconsistent with the claim that the manufacturer intended the package for sale.

(4) The manufacturer shall be limited to distributing one introductory package of each dosage strength of a product on a one-time basis to a pharmacy in order to familiarize and assure that a company's new product will be available in pharmacies. The quantity shall not be larger than one hundred solid dosage units or sixteen liquid ounces.

**246-877-020 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.

~~(4)~~ (3) A health care entity means any organization or business entity that provides medical, surgical, or dental treatment and/or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law.

**246-xxx-xxx Ephedrine prescription restrictions.**

**Commented [GCO(13]:** Should we create a definition of legend drugs?

**Commented [GCO(14R13]:** Additional language options: "Legend drug" means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "Rx only".

**Commented [GCO(15]:** Cross reference federal regulation - "Legend drug" means any drug defined by the Federal Food, Drug and Cosmetic Act, as amended, and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription." As of "x" date and will require annual updating

**Commented [GCO(16]:** Commission Discussion on difference between trade/stock packages & samples. Does the exclusion of sample in sub 3 cover the sample prohibition?

**Commented [GCO(17]:** Added based on Tim Lynch recommendation. He suggested expanding on this as well to create additional restrictions

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**Commented [GCO(18]:** Tina to review

(1) The commission, pursuant to RCW 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.

(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. | BRONCHODILATOR AND 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 HEMORRHOID suppositor (Bristol-Meyers) | 3.86 mg. ephedrine sulfate |
| 12. PAZO HEMORRHOID ointment (Bristol-Meyers) | 0.2% ephedrine sulfate |
| 13. PRIMATENE tablet (Whitehall) | 24 mg. ephedrine HCL |
| 14. PRIMATENE M tablet (Whitehall) | 24 mg. ephedrine HCL |
| 15. PRIMATENE P tablet (Whitehall) | 24 mg. ephedrine HCL |
| 16. QUELIDRINE (Abbott) | 5 mg. ephedrine HCL |
| 17. TEDRAL tablet (Parke-Davis) | 24 mg. ephedrine HCL |
| 18. THEODRINE tablet (Rugby) | 25 mg. ephedrine HCL |
| 19. VATRONOL nose drops (Vicks Health Care) | 0.5% ephedrine sulfate |

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

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

(5) Manufacturers of products containing 25 mg. or less of ephedrine per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts may

gain exemption from subsection (1) of this section if, prior to the distributing of any such product in the state of Washington, the manufacturer:

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

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

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

**246-xxx-xxx Regulated steroids.**

The commission finds that the following drugs shall be 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 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

(23) dihydrotestosterone

(24) dimethazine

(25) Drive

(26) Drolban

(27) drostanolone

(28) Durabolin

(29) Durateston

(30) Equipoise

(31) Esiclene

(32) ethylestrenol

(33) Exoboline

(34) Finaject

(35) Fluoxymesterone

(36) formebolone

(37) Halotestin

(38) Halostein

(39) Hombreol

(40) Iontanyl

(41) Laurabolin

(42) Lipodex

(43) Maxibolin

(44) mesterolone

(45) metanabol

(46) methenolone acetate

(47) methenolone enanthate

(48) methandienone

(49) methandranone

(50) methandriol

(51) methandrostenolone

(52) methyltestosterone

(53) mibolerone

(54) Myagen

(55) Nandrolin

(56) nandrolone

(57) nandrolone decanoate

(58) nandrolone cyclotate

(59) nandrolone phenpropionate

(60) Nelavar

(61) Nerobol

(62) Nilevar

(63) nisterime acetate

(64) Norbolethone

(65) Nor-Diethylin

(66) norethandrolone

(67) Normethazine

(68) Omnifin

(69) oxandrolone

(70) oxymesterone

(71) oxymetholone

(72) Parabolan

(73) Permastril

(74) pizotyline

(75) Primobolone/Primobolan depot

(76) Primotestin/Primotestin depot

(77) Proviron

(78) Quinalone

(79) Quinbolone

(80) Restandol

(81) silandrone

(82) Sostanon

(83) Spectriol

(84) stanolone

(85) stanozolol

(86) stenbolone acetate

(87) Stromba

(88) Sustanon

(89) Tes-10

(90) Tes-20

(91) Tes-30

(92) Teslac

(93) testolactone

(94) testosterone

(95) testosterone cypionate

(96) testosterone enanthate

(97) testosterone ketolaurate

(98) testosterone phenylacetate

(99) testosterone propionate

(100) testosterone undecanoate

(101) Thiomucase

(102) tibolone

(103) trenbolone

(104) trenbolone acetate

(105) trestolone acetate

(106) Trophobolene

(107) Winstrol

**246-xxx-xxx Theophylline prescription restrictions.**

The commission, pursuant to RCW 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. 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.

**246-897-020 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 ~~so~~ imported in conformity with federal regulations and/or court decisions.

**246-897-060 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.

**OTC – HOLD**

**New Controlled Substances Language**

**WAC 246-XXX-300 Precursor Substance Control (Existing chapter 246-899 suggest amending as staging for RCW similar to CSA)**

(1) For the purpose of this chapter a precursor substance is any of the following substances or their salts or isomers:

(a) Gamma-butyrolactone (GBL);

(b) 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 or 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-XXX-305 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 246-889-300 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: 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-XXX-310 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(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) ~~days notice~~day's notice.

**246-XXX-315 Suspicious transactions and reporting requirements.**

(1) A ~~manufacturer or wholesaler~~manufacturer, wholesaler or distributor who sells, transfers, or furnishes a regulated product to any licensee shall report any suspicious transaction in writing to the ~~state pharmacy quality assurance commission (commission).~~commission. For the purpose of this rule, a regulated product is defined as a product specified in RCW 69.43.010(1) or WAC 246-889-020.

**Commented [GCO(19]:** Update reference

**Commented [GCO(20]:** Added distributor from Operational Standards

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(2) 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 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.)

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

(3) Pharmacy Reporting Requirements

~~(c)~~(a) Significant losses or disappearances of controlled substances and the facts surrounding the discrepancy shall be reported to the commission, the drug enforcement agency, the chief executive officer of the hospital and other appropriate authorities.

**246-XXX-325 Requirements for the sale of 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 246-889-095 in the record of transaction before completing the sale.

**246-XXX-330 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.

**Commented [BD(22]:** Combine under regulated products

**Commented [GCO(23]:** Added from Hospital Standards

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**Commented [BD(24]:** Correct WAC reference according to changes

**Commented [BD(25]:** 21 CFR 1310

(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-XXX-340 Maintenance of and access to retail sales records of restricted products.**

(1) The retail sales records required under WAC 246-889-095 are confidential and accessible by the ~~pharmacy quality assurance~~ commission and law enforcement agencies. Law enforcement may access the retail sales records for criminal investigations when, at a minimum, there is an articulated individualized suspicion of criminal activity.
(2) Each law enforcement agency's administrator, chief, sheriff, or other chief executive officer shall ensure:
(a) Only authorized employees have access to the databases;
(b) Each employee use his or her unique password or access code to access the databases;
(c) Each employee adheres to all state and federal laws regarding confidentiality; and
(d) As employees change, new passwords or access codes are assigned to new employees and passwords of ex-employees or transferred employees are removed.
(3) Retail sales records of restricted products, electronic or written, must be kept for a minimum of two years.
(4) Retail sales records must be destroyed in a manner that leaves the record unidentifiable and nonretrievable.

**Part 3 Prescription & Labeling**

**Prescription Format**

**WAC 246-XXX-XX8 Prescription Drug Order: Minimum Requirements.**

**Except as differentiation is permitted for an institutional drug order, a prescription drug order 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:**

**(a) If for a controlled substance, the patient's full name and address; and**

**(b) 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:**

**(a) If written in Washington State complies with RCW 18.64.500 ;**

**(b) Prescriber's name is pre-printed, stamped or hand-printed;**

**(c) Wet signature of the prescriber or, if statutorily allowed, the prescriber's agent's signature; and**

**(d) If electronic, the prescriber's electronic signature.**

**(7) An institutional drug order may exempt the patient's address, quantity, prescriber's address, and prescriber's DEA registration.**

**WAC 246-XXX-XX6 Prescription Drug Order: Validity.**

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

**(a) 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.**

**(b) A prescription drug order is invalid after its expiration date as follows:**

**(i) 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.**

**(ii) 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.**

**(iii) 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.**

**Commented [BD(26]:** May need to reference RCW 69.41

4 – new 3 verify if in CS rules

**Commented [GCO(27]:** Is this correct?

**Electronic Communication of Prescription Information**

**Commented [GCO(28]:** This section has been updated from a revision done in 2016, per Steve Anderson's suggestion.

HOLD based on potential legislative change

**WAC 246-869-210 Prescription 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, 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:

(a) The nature of the drug;

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

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

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

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

(f) Any other relevant factors.

(2) In additional to (1) The dispenser shall, ~~on taking into account the foregoing~~, 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.

~~(2)~~(3) The quantity of drug dispensed, for example the volume or number of dosage units.

~~(3)~~(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."

~~(4)~~(5) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220.

**Part 4 – Unnamed so far**

**246-905-020 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 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:

(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.

**246-905-030 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.

**246-905-040 Records.**

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(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.

**246-905-050 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.