# EXPEDITED RULE MAKING

## CR-105 (December 2017)
## (Implements RCW 34.05.353)

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STATE OF WASHINGTON
FILED

DATE: November 20, 2023
TIME: 5:41 PM

WSR 23-23-153

**Agency:** Department of Health - Pharmacy Quality Assurance Commission

**Title of rule and other identifying information:** Citation and technical changes to pharmacy rules in chapter 246-945 WAC. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-001, 246-945-011, 246-945-014, 246-945-018, 246-945-063, 246-945-156, 246-945-170, 246-945-173, 246-945-175, 246-945-200, 246-945-217, 246-945-230, 246-945-417, and 246-945-590 to remove and replace citations to rules that have been repealed and make general grammatical and technical corrections.

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The commission completed rulemaking in 2020, consolidating multiple chapters of rules that regulate the practice of pharmacy into one chapter, chapter 246-945 WAC. This proposal will remove citations to repealed WAC chapters, update citations to the current governing WAC chapter or specific rule(s) and make general grammatical corrections without making any material changes.

**Reasons supporting proposal:** Following the rules consolidation project that resulted in the creation of chapter 246-945 WAC in 2020, the commission discovered a number of cross-references that are now outdated. The Secretary also finalized updated fees for commission licensees since that time and updates are now needed to correct all fee rule references.

**Statutory authority for adoption:** RCW 18.64.005

**Statute being implemented:** RCW 18.64.005

**Is rule necessary because of a:**

| | | |
|---|---|---|
| Federal Law? | ☐ Yes | ☒ No |
| Federal Court Decision? | ☐ Yes | ☒ No |
| State Court Decision? | ☐ Yes | ☒ No |

If yes, CITATION:

**Name of proponent:** (person or organization) Washington State Pharmacy Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

**Name of agency personnel responsible for:**

| | Name | Office Location | Phone |
|---|---|---|---|
| Drafting: | Joshua Munroe | 111 Israel Rd SE, Tumwater, WA 98501 | 360-502-5058 |
| Implementation: | Joshua Munroe | 111 Israel Rd SE, Tumwater, WA 98501 | 360-502-5058 |
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**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** None.

**Expedited Adoption - Which of the following criteria was used by the agency to file this notice:**

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☐ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☒ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

**Expedited Repeal - Which of the following criteria was used by the agency to file notice:**

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

**Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4):** The commission believes the expedited rulemaking process is appropriate as the proposed rules fall under RCW 34.05.353(1)(c) since they "correct typographical errors... and clarify language of a rule without changing its effect." The updating of references from older repealed sections of rule to the current active sections of rule does not represent a substantive change to any regulation under the commission's jurisdiction.

**NOTICE**

**THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO**

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**AND RECEIVED BY** (date) 1/22/2024

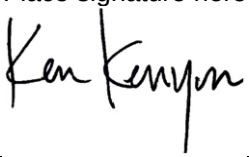
**Date:** November 20, 2023

**Name:** Kenneth Kenyon, PharmD, BCPS

**Title:** Pharmacy Quality Assurance Commission Chair

**Signature:**

Place signature here



AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) "Consultation" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(43) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system,

where the physical address of the office or clinic is identified on a hospital pharmacy license.

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

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

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

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

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

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

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

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

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

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

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

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

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

(55) "NDC" means National Drug Code.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) The maintenance of radiopharmaceutical quality assurance;

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

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

(69) "Radiopharmaceutical" means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(70) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

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

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

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

(74) "Strength" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any ((~~twelve~~)) 12 consecutive month period.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

(2) A prescription shall be considered invalid if:

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

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

(c) The prescription is expired; or

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

(3) A prescription is considered expired when:

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

(b) The prescription is for a noncontrolled legend drug or ((~~OTC's~~)) OTC and the date of dispensing is more than ((~~twelve~~)) 12 months after the prescription's date of issue.

AMENDATORY SECTION (Amending WSR 21-17-062, filed 8/11/21, effective 9/11/21)

**WAC 246-945-014 Electronic prescribing mandate waiver.** (1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other ex-

ceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312 (2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312 (2)(k).

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

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

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

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

(a) Economic hardship in the following circumstances:

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

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

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

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of ((~~thirty~~)) 30 percent medicaid patients.

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

(c) Other exceptional circumstances include:

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

(ii) The practitioner generates fewer than ((~~one hundred~~)) 100 prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;

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

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

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Knowingly submitting a false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

(1) Drug name;

(2) Drug strength;

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

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

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

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

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

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

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

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

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

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

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

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

(2) To request a temporary practice permit, the pharmacy intern applicant shall submit a written request for a temporary practice permit, and any applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacy intern registration is issued;

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

(c) Ninety days after the temporary practice permit is issued. The applicant may obtain a one-time extension of up to ((~~ninety~~)) 90 days with approval of the commission.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

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

(b) Take and pass the approved jurisprudence examination.

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

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

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

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

(d) To request a temporary practice permit, the applicant shall submit a written request for a temporary practice permit, and pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacist license is issued;

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

(c) One hundred eighty days after the temporary practice permit is issued. The applicant may obtain a one-time extension of ((~~one hundred eighty~~)) 180 days with approval of the commission.

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

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-173 Expired pharmacist license.** To return to active status a pharmacist with an expired license shall pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 and:

(1) If the pharmacist license has been expired for less than three years the pharmacist shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040 and ((~~fifteen~~)) 15 CPE hours per year the license has been expired.

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

(a) Meet the requirements ((~~in chapter 246-12 WAC, Part 2~~)) of WAC 246-12-040;

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

(i) Name and license number;

(ii) Issue and expiration date; and

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

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

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

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

(a) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040;

(b) Serve an internship of ((~~three hundred~~)) 300 hours in compliance with WAC 246-945-163; and

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

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

(2) An inactive license can be renewed in accordance with ((~~chapter 246-12~~)) WAC 246-12-100 and by paying the applicable fees in accordance with WAC 246-945-990 through 246-945-992.

(3) If a license is inactive for three years or less, to return to active status a pharmacist shall meet the requirements of ((~~chapter 246-12 WAC, Part 4~~)) WAC 246-12-110.

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

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

(i) Name and license number;

(ii) Issue and expiration date; and

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

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

(c) Meet the requirements of ((~~chapter 246-12 WAC, Part 4~~)) WAC 246-12-110; and

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

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

AMENDATORY SECTION (Amending WSR 23-09-062, filed 4/18/23, effective 5/19/23)

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

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

(3) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with WAC 246-945-990 through 246-945-992.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-217 Expired pharmacy technician certification.** To return to active status a pharmacy technician with an expired certification shall pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992, and:

(1) If a pharmacy technician's certification has expired for five years or less, the pharmacy technician shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

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

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

(b) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

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

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

(b) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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

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

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

(2) The commission shall license a facility that:

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

(b) Pays the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992. This fee will not be prorated under any circumstances;

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

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

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

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

(b) Submit a new application on forms provided by the commission and pay the ((~~original~~)) initial license fee as established in ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the ((~~original~~)) initial license fee in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than ((~~fifty~~)) 50 percent ownership in a corporation.

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

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

(d) Notify the commission within ((~~thirty~~)) 30 days of any changes to the information provided on their application.

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

(f) Renew their license in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

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

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-417 Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records.** (1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care.

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

(b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services.

(2) The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible.

(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:

(a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and

(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.

(4) The pharmacy shall have policies and procedures in place for system downtime.

(a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter.

(b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed.

(c) This section does not require that a permanent dual recordkeeping system be maintained.

(5) The pharmacy shall maintain records in accordance with WAC 246-945-020.

(6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311.

(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections ((~~(2)~~)) (1) through ((~~(7)~~)) (6) of this section.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-590 Wholesaler—Policies and procedures.** Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies ((~~as required to the FDA, commission and/or appropriate federal or state agency~~)) to the FDA, commission, and, as applicable, the DEA upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC ((~~246-960-330~~)) 246-945-585; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.