WSR 26-13-027
PERMANENT RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed June 9, 2026, 9:40 a.m., effective July 10, 2026]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Incorporation by reference of federal statutes or regulations and national consensus codes in pharmacy rules. The pharmacy quality assurance commission (commission) adopted amendments to update references to regulations from other entities that have been incorporated into chapter 246-945 WAC that do not change the effect of the rule. The amendments include cross references to federal regulations in the following rules:

- WAC 246-945-010 to incorporate the updated Title 21 C.F.R. Parts 1300 through 1399;
- WAC 246-945-030 to incorporate the updated United States Food and Drug Administration "Orange Book," "Green Book," and "Purple Book";
- WAC 246-945-032 to incorporate the updated 16 C.F.R. § 1700.14;
- WAC 246-945-040 to incorporate the updated 21 C.F.R. § 1301.12;
- WAC 246-945-550 to incorporate the updated 21 C.F.R. Parts 210 and 211;
- WAC 246-945-565 to incorporate the updated United States Pharmacopeia—National Formulary; and
- WAC 246-945-600 to incorporate the updated 21 C.F.R. Parts 207, 210, and 211, Subpart K.

Citation of Rules Affected by this Order: Amending WAC 246-945-010, 246-945-030, 246-945-032, 246-945-040, 246-945-550, 246-945-565, and 246-945-600.

Statutory Authority for Adoption: RCW 18.64.005, 69.41.075, and 69.50.201.

Adopted under notice filed as WSR 26-05-078 on February 17, 2026.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 7, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 4, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 7, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 7, Repealed 0.

Date Adopted: June 9, 2026.

Hawkins DeFrance, PharmD, Chair
Pharmacy Quality Assurance Commission

RDS-6886.2

AMENDATORY SECTION (Amending WSR 24-21-069, filed 10/11/24, effective 11/11/24)

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

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

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

(a) Prescriber's name;

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

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

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

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

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

(4) A prescription for a controlled substance must include all the information listed in subsection (3) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of ((~~March 7, 2024~~)) January 1, 2026.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of ((~~March 7, 2024~~)) January 1, 2026.

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

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

(b) If a Schedule II drug is dispensed in an emergency, the practitioner shall 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 shall note on the prescription that it was filled on an emergency basis.

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

reduced to a written or electronic prescription that complies with WAC 246-945-011.

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

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

AMENDATORY SECTION (Amending WSR 24-21-069, filed 10/11/24, effective 11/11/24)

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

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications in effect as of ((~~March 7, 2024~~)) January 1, 2026, unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The ((~~44th~~)) 45th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The ((~~2024~~)) 2025 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The ((~~2024~~)) 2025 Purple Book: Database of FDA-Licensed Biological Products (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

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

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

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

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

WAC 246-945-032 Child-resistant containers. (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 C.F.R., Part 1700 in effect as of January 1, 2026, unless:

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

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

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

AMENDATORY SECTION (Amending WSR 24-01-102, filed 12/18/23, effective 1/18/24)

WAC 246-945-040 Uniform Controlled Substance Act. (1) The commission adopts and incorporates Title 21 of the Code of Federal Regulations in effect as of ((~~March 2, 2023~~)) January 1, 2026, by reference. The following sections of 21 C.F.R. do not apply: Sec. 6.1 - 6.5, Sec. 58.1 - 58.15, Sec. 83 - 98, Sec. 100 - 199, Sec. 225 - 226, Sec. 291, Sec. 370 - 499, Sec. 501.1 - 501.110, Sec. 502.5 - 502.19, Sec. 505, Sec. 507.1 - 507.215, Sec. 508, Sec. 509.3 - 509.30, Sec. 536, 539, 540, 544, 546, 548, 555, and 564, Sec. 556.1 - 556.770, Sec. 558.3 - 558.665, Sec. 570, 571, and 573, Sec. 579.12 - 579.40, Sec. 584, Sec. 589, Sec. 590 - 599, Sec. 601 - 607, Sec. 620, Sec. 630.1 - 630.40, Sec. 640.1 - 640.130, Sec. 650, Sec. 700 - 799, Sec. 804 - 805, Sec. 813, Sec. 897, Sec. 900, Sec. 1000 - 1050, Sec. 1100 - 1150, Sec. 1210.1 - 1210.31, Sec. 1220, Sec. 1240.3 - 1240.95, Sec. 1250.3 - 1250.96, Sec. 1251 - 1269, Sec. 1270.1 - 1270.43, Sec. 1271.1 - 1271.440, Sec. 1272 - 1299, Sec. 1301.13, Sec. 1301.28, Sec. 1301.33, Sec. 1301.35 - 1301.46, Sec. 1308.41 - 1308.45, Sec. 1316.31 - 1316.67, and Sec. 1400 through 1499. Any inconsistencies between the material incorporated by reference in this subsection and the remainder of this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(2) Copies of the reference material listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also access copies at https://www.ecfr.gov/current/title-21.

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

(4) Recordkeeping and inventory. Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Regis-

trants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:

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

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

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

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

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

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

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

AMENDATORY SECTION (Amending WSR 24-21-069, filed 10/11/24, effective 11/11/24)

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., Sec. 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R., Sec. 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General" in effect as of ((~~March 7, 2024~~)) January 1, 2026.

(2) Manufacturers required to register with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b (d)(4)(A) in effect as of ((~~March 7, 2024~~)) January 1, 2026, shall also comply with FDA guidance document.

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

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

AMENDATORY SECTION (Amending WSR 24-21-069, filed 10/11/24, effective 11/11/24)

WAC 246-945-565 Wholesaler—Drug storage. (1) Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by the requirements of the 43rd edition of USP and 38th edition of the National Formulary (USP/NF) in effect as of ((~~March 7, 2024~~)) January 1, 2026, to preserve product identity, strength, quality, and purity. The USP/NF is available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

(2) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Temperature and humidity recording equipment, devices, logs, or a combination thereof shall be used to document proper storage of drugs.

(4) Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area.

(5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.

(6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined.

(7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.

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

WAC 246-945-600 Salvaging and reprocessing. Wholesalers shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to prescription drug salvaging or reprocessing, including Chapter 21, Parts 207, 210, and 211k of the Code of Federal Regulations in effect as of January 1, 2026.