EXPEDITED RULE MAKING

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

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FILED

DATE: May 22, 2024
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WSR 24-11-152

Agency: Department of Health - Pharmacy Quality Assurance Commission

Title of rule and other identifying information: Incorporation by reference of federal statutes or regulations and national consensus codes in pharmacy rules. The Pharmacy Quality Assurance Commission (commission) is proposing revisions to update references to regulations from other entities that have been incorporated into chapter 246-945 WAC and to make other clarifying changes that do not change the effect of the rule.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: As well as housekeeping changes, the proposed rules amend:

- WAC 246-945-010 to incorporate the updated Title 21 of the Code of Federal Regulations (C.F.R.) Sections 1300 through 1399;
- WAC 246-945-013 to incorporate the updated 21 C.F.R. 1306.23, the updated 21 C.F.R. 1306.13, and the updated Title 21 of the United States Code (U.S.C.) Section 829;
- WAC 246-945-030 to incorporate the updated United States Food and Drug Administration (FDA) "Orange Book," "Green Book," and "Purple Book";
- WAC 246-945-550 to incorporate the updated 21 C.F.R. 210, 21 C.F.R. 211, and 21 U.S.C. 353b(d)(A); and
- WAC 246-945-565 to incorporate the updated United States Pharmacopeia – National Formulary.

The commission is also proposing to create a new section, WAC 246-945-034, to incorporate updates to FDA drug classifications by identifying drugs that would be considered over-the-counter drugs in Washington state.

Reasons supporting proposal: As currently written, WAC 246-945-010, 246-945-013, 246-945-030, 246-945-550, and 246-945-565 do not account for changes made to the federal laws and national standards incorporated by reference after chapter 246-945 WAC went into effect on July 1, 2020. The proposed rule amendments reference these new federal requirements. The commission is ensuring that substances (drugs) are classified in the same manner as federal law.

Also, since August 11, 2023, the commission has had an emergency rule in place that temporarily creates WAC 246-945-034 to clarify that certain FDA approved over-the-counter (OTC) drugs are classified as OTC in Washington state. The proposed rule would permanently adopt WAC 246-945-034 to classify the drugs approved for OTC distribution by the FDA, as listed as legend drugs in the Orange Book, as an OTC drug in Washington state.

The proposed rule language qualifies for expedited rulemaking under RCW 34.05.353(1)(b) as the language would incorporate by reference federal statutes or regulations and national consensus codes that generally establish industry standards without material change.

Other housekeeping changes have been made to provide clarifications without changing the effect of the rules.

Statutory authority for adoption: RCW 18.64.005, 69.41.075, and 69.50.201.

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:

U.S. Code (March 7, 2024). *USC – United States Code Title 21*. https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-2015-title21&saved=%7CZ3JhbnVsZWlkOlVTQy0yMDE1LXRpdGxlMjEtc2VjdGlvbjgyOQ%3D%3D%7C%7C%7C0%7Cfalse%7C2015&edition=2015

U.S. Food & Drug Administration (March 7, 2024). *CFR - Code of Federal Regulations Title 21*. https://www.ecfr.gov/current/title-21/chapter-II/part-1306?toc=1

U.S. Food & Drug Administration (March 7, 2024). Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book." https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book

U.S. Food & Drug Administration (March 7, 2024). Approved Animal Drug Products "Green Book." https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book

U.S. Food & Drug Administration (March 7, 2024). 2024 List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book." https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or

Name of proponent: Washington State Pharmacy Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
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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 proposed amending language incorporates by reference federal statutes and regulations without material

change in WAC 246-945-010, 246-945-013, 246-945-030, 246-945-550, 246-945-565, and new WAC 246-945-034. The proposed amendments acknowledge changes to the incorporated references made after the effective dates of chapter 246-945 WAC.

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) 07/22/2024

Date: 05/22/2024 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Chair	**Signature:** 

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

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 ((~~(1)~~)) (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.((~~, Chapter II~~)) Secs. 1300 through 1399 in effect as of March 7, 2024.

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

(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 ((~~must~~)) 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 ((~~must~~)) 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 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-013 Partial filling of prescriptions. (1) A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that:

(a) The partial fill is requested by the patient or the prescriber;

(b) The partial filling is recorded in the same manner as a refilling;

(c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and

(d) Partial fills for controlled substances listed in Schedule III through V comply with 21 C.F.R. Sec. 1306.23 in effect as of March 7, 2024.

(2) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 C.F.R. Sec. 1306.13 in effect as of March 7, 2024, as applicable.

(3) 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 20-12-072, filed 6/1/20, effective 7/1/20)

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, unless the drug is

identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The ((~~39th~~)) 44th 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 ((~~2019~~)) 2024 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 ((~~2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"*~~)) 2024 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.

NEW SECTION

WAC 246-945-034 Identification of the over-the-counter drugs. (1) The commission identifies the following as an over-the-counter drug in Washington:

(a) 4 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(b) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(2) Any conflicts between this section and the publications incorporated by reference in WAC 246-945-030(2) should be resolved in favor of this section.

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

WAC 246-945-550 Manufacturers—Minimum standards. (1) Manufacturers shall comply with the applicable requirements in 21 C.F.R., ((~~Part~~)) Sec. 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; and 21 C.F.R.,

((~~Part~~)) Sec. 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals; General((~~.~~))" in effect as of March 7, 2024.

(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, 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 20-12-072, filed 6/1/20, effective 7/1/20)

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, 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, ((~~and/or~~)) 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.