

WSR 23-22-035

EXPEDITED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed October 23, 2023, 1:49 p.m.]

Title of Rule and Other Identifying Information: Updating reference to United States Pharmacopeia (USP) General Chapters 795 and 797. The pharmacy quality assurance commission (commission) is proposing a revision to WAC 246-945-100 Compounding minimum standards, to update the rule to the most recent version of the USP - National Formulary <795> and <797>.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The proposed rule amends WAC 246-945-100 to update the rule to the most recent versions of the USP <795> and <797>. USP <795> and <797> were adopted into rule by reference effective on July 1, 2020. Since then, USP <795> and <797> have been updated.

Reasons Supporting Proposal: The existing reference in WAC 246-945-100 does not account for changes made to USP <795> and <797> that are official as of November 1, 2023, by USP. The proposed rule updates the references to the most recent versions. The proposed rule language qualifies for expedited rule making under RCW 34.05.353 (1)(b) as the language incorporates by reference national standards without material change.

Statutory Authority for Adoption: RCW 18.64.005.

Statute Being Implemented: RCW 18.64.005 and 18.64.270.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Haleigh Mauldin, 111 Israel Road S.E., Tumwater, WA 98501, 360-890-0720; Enforcement: Marlee O'Neill, 111 Israel Road S.E., Tumwater, WA 98501, 360-480-9180.

This notice meets the following criteria to use the expedited adoption process for these rules:

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.

Explanation of the Reason the Agency Believes the Expedited Rule-Making Process is Appropriate: The proposed amendments adopt by reference, without material change, the most recent version of the national standard, USP <795> and <797>. The national standard is adopted by reference in existing rule. The proposed amendments update the rule to the most recent version of the national standard.

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 Haleigh Mauldin, Pharmacy Quality Assurance Commission, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-890-0720, email PharmacyRules@doh.wa.gov, <https://fortress.wa.gov/doh/policyreview>, AND RECEIVED BY January 2, 2024.

October 23, 2023
Kenneth Kenyon, PharmD, BCPS
Pharmacy Quality Assurance Commission

OTS-4925.1

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

WAC 246-945-100 Compounding minimum standards. (1) All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration:

- (a) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations, official as of November 1, 2023;
- (b) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations, official as of November 1, 2023;
- (c) USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings; and
- (d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) Copies of the USP General Chapters 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 contact USP directly to obtain copies.