



EXPEDITED RULE MAKING

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

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STATE OF WASHINGTON
FILED

DATE: October 23, 2023

TIME: 1:49 PM

WSR 23-22-035

Agency: Department of Health – Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) 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 rulemaking 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

Is rule necessary because of a:

- | | | |
|-------------------------|------------------------------|--|
| Federal Law? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Federal Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| State Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |

If yes, CITATION:

Name of proponent: (person or organization)

- 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
Implementation:	Haleigh Mauldin	111 Israel Rd SE, Tumwater WA 98501	360-890-0720
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater WA 98501	360-480-9180

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 amendments adopt by reference, without material change, the most recent version of the national standard, USP <795> and USP <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

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AND RECEIVED BY (date) 1/2/2024

Date: October 23, 2023

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission

Signature:



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 - Non-sterile 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.