

WSR 24-09-051

PERMANENT RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed April 15, 2024, 11:04 a.m., effective May 16, 2024]

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

Purpose: Updating reference to United States Pharmacopeia (USP) General Chapters 795 and 797. The pharmacy quality assurance commission (commission) adopted 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>. This will capture the revisions to the USP <795> and <797>, which have been made official since WAC 246-945-100 became effective on July 1, 2020.

Citation of Rules Affected by this Order: Amending WAC 246-945-100.

Statutory Authority for Adoption: RCW 18.64.005.

Adopted under notice filed as WSR 23-22-035 on October 23, 2023.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 1, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0.

Date Adopted: April 15, 2024.

Ken Kenyon, PharmD, BCPS, Chair
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.