RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 15, 2024
TIME: 11:04 AM

WSR 24-09-051

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

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:

New: None
Repealed: None
Amended: WAC 246-945-100
Suspended: None

Statutory authority for adoption: RCW 18.64.005

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

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

Describe any changes other than editing from proposed to adopted version: No changes were made from the proposed to the adopted version.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The 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Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	1	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	1	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	1	Repealed	0

Date Adopted: 4/15/2024

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission Chair

Signature: 

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.