



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
Olympia, Washington 98504

## NOTICE OF ADOPTION OF A POLICY STATEMENT

**Title of Policy Statement:** Enforcement of USP General Chapters <795>, <797>, <800>, and <825> | Policy Statement P010

**Issuing Entity:** Pharmacy Quality Assurance Commission

**Subject Matter:** This policy clarifies the Pharmacy Quality Assurance Commission's approach to United States Pharmacopeia General chapters <795>, <797>, <800>, and <825> as it relates to WAC 246-945-100 and RCW 18.64.270(2).

**Effective Date:** November 1, 2023

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**WSR 23-23-041**

**Department of Health**  
**Pharmacy Quality Assurance Commission**

# Policy Statement

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|------------------------|---|---------------------|
| <i>Title:</i>          | Enforcement of USP General Chapters <795>, <797>, <800>, and <825>  | <i>Number:</i> P010 |
| <i>References:</i>     | <a href="#">RCW 18.64.270(2)</a> ; <a href="#">WAC 246-945-100</a> ; United States Pharmacopeia General Chapters <795>, <797>, <800>, and <825> |                     |
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| <i>Effective Date:</i> | November 1, 2023  |                     |
| <i>Supersedes:</i>     | N/A   |                     |
| <i>Approved By:</i>    | Ken Kenyon, PharmD, BCPS<br>Pharmacy Quality Assurance Commission Chair   |                     |

As of November 1, 2023, the Pharmacy Quality Assurance Commission (commission) will require licensees who engage in compounding to comply with, among other things, the following chapters of the United States Pharmacopeia (USP) as applicable:

- USP General Chapter <795>, with official date of November 1, 2023;
- USP General Chapter <797>, with official date of November 1, 2023;
- USP General Chapter <800>, with official date of December 1, 2019; and
- USP General Chapter <825>, with official date of December 1, 2020<sup>1</sup>.

RCW 18.64.270(2) requires that compounded sterile and nonsterile products meet the standards of the “official United States pharmacopeia.” Additionally, WAC 246-945-100 identifies those USP chapters that licensees of the commission are required to comply with when engaged in sterile and nonsterile compounding.

Over the last four years, USP has published, and made official, revised versions of USP General Chapters <795>, <797>, <800>, and <825>. The revised USP General Chapter <800> became official on December 1, 2019; the revised General Chapter <825> became official on December 1, 2020; and the revised General Chapters <795> and <797> will become official on November 1, 2023.

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<sup>1</sup> The commission has required licensees to comply with USP General Chapter <825> since October 1, 2021.

Based on the revisions to the USP General Chapters, the commission will require licensees who engage in nonsterile or sterile compounding to be in compliance with all the revised USP General Chapters, as required by RCW 18.64.270(2) and WAC 246-945-100, by November 1, 2023.

Finally, the commission has initiated an expedited rulemaking project under WSR 23-22-035 to amend WAC 246-945-100 to convert this policy statement into rule.