Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Enforcement of USP Chapters <800> and <825> *Number: 65.4*
References:	RCW 18.64.270(2); WAC 246-945-016, WAC 246-945-017, WAC 246-945-100, and WAC 246-945-490; United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>; Commission Policy #60.1
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Supersedes:	Policy 65.3 effective April 1, 2022
Approved By:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair

This policy clarifies the Pharmacy Quality Assurance Commission's (commission) approach to United States Pharmacopeia (USP) chapters <800> (USP 800) and <825> (USP 825) as it relates to WAC 246-945-100 and RCW 18.64.270(2).

During the March 24, 2022, business meeting, the commission voted to continue its position that it will not find deficiencies or take enforcement action against licensees for failure to comply with USP 800 through September 30, 2022. At the September 23, 2022, business meeting, the commission voted to extend its enforcement discretion of USP 800 until it is withdrawn by the commission at an open public meeting.

Compliance requirements for USP 825 began October 1, 2021, where applicable, per WAC 246-945-100 and RCW 18.64.270(2).

The revised USP chapters <795> (USP 795) and <797> (USP 797) will not be official until November 1, 2023. The commission will consider its use of enforcement discretion for USP 800 during this time. Any decision to modify the commission's use of enforcement discretion for USP 800 will be made during an open public meeting.

Standards for hazardous drug compounding were supposed to be eliminated in the initial proposed revision to USP 797 and only exist in USP 800. The delay in formal adoption or release of an updated revision draft for USP 797 created some direct conflicts between the two chapters. For those licensees who choose to become early adopters of USP 800, the commission's

approach to the discrepancies between USP 797 and USP 800 can be found in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website. Policy Statement #60.1 also explains adherence to the Washington State Department of Labor and Industries' (L&I) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

Table of PQAC's Enforcement Discretion Timeline	
USP Chapters	Enforcement Discretion
USP 800	October 1, 2020 – TBA
USP 825	October 1, 2020 – September 30, 2021
Revised USP 795 and 797	Revised chapters were released on November 1, 2022 but are not official until November 1, 2023. Any decision(s) related to the revised chapters will be made at an open public meeting.
Current USP 795 and 797	These chapters will continue to be enforced.

Note: Please see Policy #60.1 regarding direct conflicts between USP 797 and USP 800.

In 2013, the Washington State Legislature adopted standards set by USP as the standards pharmacies must meet when sterile or non-sterile compounding. RCW 18.64.270(2) states, "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." As a result, the commission has enforced standards published by USP for sterile and non-sterile compounding since 2014.

The commission's new rule chapter (chapter 246-945 WAC) went into effect on July 1, 2020. This chapter rewrite took place over two and half years and included extensive collaboration with interested parties.

The new chapter includes enforcement of USP standards in accordance with RCW 18.64.270(2). Specifically, WAC 246-945-100 Compounding minimum standards requires that licensees comply with USP chapters 795, 797, 800, and 825. There are additional requirements for labeling compounded products in WAC 246-945-016 and WAC 246-945-017. WAC 246-945-490(3) and (4) also require nuclear pharmacies to prepare, compound, and dispense radiopharmaceuticals in accordance with the standards in USP 825.

The commission recognizes there are discrepancies between USP 797 and USP 800 in its current form; however, its approach to these discrepancies as well as adherence to L&I's rules on Hazardous Drugs (WAC 296-62-500 *et al)* is established in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website. The commission also recognizes that the revised USP 795 and 797 are available, but not official until November 1, 2023. Any decisions related to the enforcement discretion of USP 800 will be made at an open public meeting.