Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

Title:	Enforcement of USP Chapters <800> and <825>	*Number: 65.2*
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	
Contact:	Lindsay Trant, Interim Deputy Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	October 1, 2021	
Supersedes:	Policy 65.1 effective April 1, 2020	
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).

At its September 2, 2021 business meeting, the commission voted to continue its position that it will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 800 through March 31, 2022.

The commission expects compliance with USP 825 beginning October 1, 2021 where applicable, per WAC 246-945-100 and RCW 18.64.270(2).

When appropriate, the commission will revisit its use of enforcement discretion for USP 800. Any decision to modify the commission's use of enforcement discretion for USP 800 will be during an open public meeting before March 31, 2022.

The commission will consider extending its use of enforcement discretion for USP 800 if USP has not made the revised USP chapters <795> (USP 795) and <797> (USP 797) official. Additionally, if USP makes the revised USP 795 and USP 797 official prior to March 31, 2022, the commission will consider whether to extend its use of enforcement discretion for an additional period of time.

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 has created some direct conflicts between the two chapters. The commission has considered and may revisit the delayed enforcement of USP 800 until the revised USP 795 and USP 797 are official to avoid licensees being subject to USP

standards that conflict with each other. 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' (LNI) 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 – March 31, 2022
USP 825	October 1, 2020 – September 30, 2021
Revised USP 795 and 797	N/A; Revised Chapters have not been released
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 LNI'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.

If USP makes the revised USP 795 and USP 797 official prior to March 31, 2022, the commission will consider whether to extend its use for enforcement discretion on USP 800 for an additional period of time to allow licensees to comply with all applicable USP chapters at a future open public meeting.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

PO Box 47890 • Olympia, Washington 98504-7890
Tel: (360) 236-4501 • FAX: (360) 586-7424 • TDD Relay Service: 1-800-833-6388

NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Enforcement of USP Chapters <800> and <825> | Policy Statement 65.2

Issuing Entity: Pharmacy Quality Assurance Commission

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

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Contact Person: Lindsay Trant
Interim Deputy Director,
Pharmacy Quality Assurance Commission,
Washington State Department of Health
(360) 236-4946
wspqac@doh.wa.gov

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