

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

<i>Title:</i>	Regulation of the Handling of Hazardous Drugs	<i>Number:</i> 60.1
<i>References:</i>	RCW 18.64.270(2), WAC 246-945-016 , WAC 246-945-017 , WAC 246-945-100 United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>, Commission Policy #65	
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<i>Effective Date:</i>	October 1, 2020	
<i>Supersedes:</i>	Policy Number 60, Effective February 2, 2018	
<i>Approved By:</i>	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

This policy updates the original policy that took effective February 2, 2018 and continues to identify the approach of the Pharmacy Quality Assurance Commission (commission) as it relates to direct conflicts between United States Pharmacopeia (USP) chapters <797> (USP 797) and <800> (USP 800). This policy also attempts to clarify uncertainty related to USP 797, USP 800, and the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al*).

The commission will not find deficiencies or take enforcement action against its licensees for adhering to the standards of USP 800 that are in direct conflict with USP 797. For those conflicts identified in the table below, licensees must adhere to the provision in either USP 797 or USP 800.

After consultation with LNI, it has been determined if licensees choose to adopt USP 800 including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al*).

BACKGROUND: Following a 2012 meningitis outbreak stemming from unsterile compounding at the New England Compounding Center in Massachusetts, several states worked to adopt standards around sterile and non-sterile compounding of medications. In 2013, the Washington State legislature adopted standards set by the USP, a national leader in compounding standards, as the standards pharmacies must meet in order to compound medication. 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.” The USP is a non-governmental organization that establishes national consensus standards and guidelines for the pharmaceutical industry.

The commission has enforced standards published by USP for sterile and non-sterile compounding since 2014. Sterile compounding standards are currently published in USP 797 and non-sterile compounding standards are published in USP chapter <795> (USP 795). In September 2015, when a revision to USP 797 was published for public comment, it was anticipated that a finalized update would be published sometime in 2016, and subsequently made official sometime in 2017. Due to the large number of comments received by the USP, the final publication of the update has been delayed several times.

During the revision process for USP 797, the USP developed and adopted USP 800, which addresses the handling of hazardous drugs in healthcare settings. USP 800 was initially projected to go into effect on July 1, 2018. This delayed effective date was intended to allow facilities that would need to go through renovations or new construction some additional time to become compliant with USP 800. 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.

At this time, the commission has identified the following provisions of USP 797 and USP 800 that are in direct conflict:

USP 797	USP 800
<p>All hazardous drugs shall be prepared in a BSC [biological safety cabinet] or a CACI [compounding aseptic containment isolator] that meets or exceeds the standards for CACI in this chapter. The ISO [international organization for standardization] Class 5 [] BSC or CACI shall be placed in an ISO Class 7 [] area that is physically separated . . . <u>(Hazardous Drugs as Compounded Sterile Preparations).</u></p> <p>If the PEC [primary engineering control] is a CAI [compounding aseptic isolator] or a CACI that does not meet the requirements above or is a LAFW [laminar airflow workbench] or BSC that cannot be located within an ISO Class 7 [] buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs [compounded sterile preparations] pursuant to a physician order for a specific patient may be prepared, and administration of the CSP</p>	<p>The C-PEC [containment primary engineering control] must be located in a C-SEC [containment secondary engineering control], which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified [containment] segregated compounding area (C-SCA). <i>(5.3.2 Sterile Compounding).</i></p>

<p>shall commence within 12 hours of preparation or as recommend in the manufacturer’s package insert, whichever is less. (<i>Placement of Primary Engineering Controls</i>).</p>	
<p>In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., a CSTD [closed-system drug-transfer system] within a BSC or CACI that is located in a non-negative pressure room) is acceptable. (<i>Hazardous Drugs as CSPs</i>).</p>	<p>Elimination of the current allowance in <797> for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. (<i>USP 800 Briefing</i>).</p>

These direct conflicts have created uncertainty amongst licensees as to which standard the commission will enforce at inspections or in disciplinary action.

On September 29, 2017, the USP announced a delay in the official effective date of USP 800, postponing it from July 1, 2018 to December 1, 2019. However, USP postponed enforcement while appeals on related provisions in USP <795> and <797> are resolved. During this appeals process, USP <800> will be “informational and not compendial applicable, USP encourages utilization of <800> in the interest of advancing public health.”

Several licensed facilities in Washington State have already sought capital expenditures from their organizations to begin renovation or new construction to comply with USP 800. The commission wishes to encourage its licensees to comply with USP 800, rather than risk being found deficient or subject to enforcement action because USP 800 standards reflect safer handling of hazardous drugs, ensuring patients receive the highest quality hazardous drug products.

While examining its position on direct conflicts between USP 797 and USP 800, the commission also analyzed potential areas of conflict between USP 797, USP 800 and LNI’s General Occupational Health Standards rules on Hazardous Drugs (*WAC 296-62-500 et al*). During this analysis, LNI expressed to the commission that if the commission’s licensees adopt USP 800, including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI’s rules.

CONCLUSION: The commission will not take enforcement action on a licensee if the licensee adheres to USP 800 standards that are in conflict with current USP 797 standards. For those conflicts identified in the table above, licensees must adhere to the provision in either USP 797 or USP 800. The commission believes USP 800 furthers the commission’s mission of ensuring patient safety, particularly in the compounding of hazardous drugs.

In addition, licensees may elect to adopt USP 800 standards prior to the commission’s enforcement of the chapter. In doing so, the commission will not find deficiencies or take

enforcement action against its licensees for adhering to the standards of USP 800 that are in direct conflict with USP 797. This provision will allow for adequate time to plan for capital and process changes to meet proposed USP standard changes. For clarification of enforcement for USP 800 and USP 825, please reference companion policy statement (#65).

If licensees choose to adopt USP 800 including those sections of USP 800 that are in conflict with USP 797 they will also be compliant with LNI's General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al*).



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
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NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Regulation of the Handling of Hazardous Drugs
Policy Number 60.1

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This policy establishes the approach of the Pharmacy Quality Assurance Commission as it relates to direct conflicts between United States Pharmacopeia chapters <797> and <800>. This policy also attempts to clarify uncertainty related to USP 797, USP 800 and the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al*).

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