**Commission SBAR Communication**

**Agenda Item/Title:** Interpretive Statement on Storage of Hazardous Drug Compounding Materials under USP <800> - Hazardous Drug Handling – FINAL Approval

**Date SBAR Communication Prepared:** September 5, 2019

**Reviewer:** Tracy West, Deputy Director (with support from Christopher Gerard, AAG)

**Link to Action Plan:**

- Action
- Information
- Follow-up
- Report only

**Situation:** At the December 2018 business meeting, the commission discussed and agreed that USP <800> does not require a separate storage room for hazardous drugs or materials used in the compounding of hazardous drugs. Staff were instructed to draft an interpretive statement regarding the issue. At the January 2019 meeting, the Commission asked that staff add clarity and examples to the document. At the March 2019 meeting the Commission approved the draft language. After review by DOH minor changes have been made, including eliminating headers, spelling out acronyms and minor grammatical edits.

**Background:**

In Washington, individuals and facilities licensed by the Commission are required by statute to comply with the standards of the official USP as it applies to compounding of nonsterile and sterile products (RCW 18.64.270(2). The Commission has interpreted this provision to require individuals and facilities to comply with USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and USP 797. The Commission has indicated that USP 800 will become required once made official by USP.

The Commission has formalized a policy statement allowing early adoption of USP 800 in Washington for facilities licensed under RCW 18.64. This was because the Commission felt compliance with USP 800 would ensure patient safety and promote public health, and allow licensed facilities to begin any necessary upgrades.

Until USP makes the proposed USP 797 and USP 800 official, the Commission has had to grapple with potential conflicts between the current USP 797 and the proposed USP 800 (specifically for those licensed facilities who are adopting USP 800 early). See, for example Policy Statement Number 60 – Regulation of the Handling of Hazardous Drugs.

**Assessment:**

Staff worked with AAG Christopher Gerard, and stakeholders to provide examples in the Interpretive Statement. Additionally, department of health policy staff have reviewed and provided minor edits for Commission consideration and approval.

**Recommendation:**

1. The Commission should adopt the interpretive statement as amended, and direct staff to file with the code reviser.
2. The Commission should make changes as the Commission deems appropriate.
3. The Commission can direct staff to do additional research or work on the interpretive statement.
This interpretive statement establishes the approach of the Pharmacy Quality Assurance Commission (Commission) as it relates storage requirements of hazardous drugs (HD) under United States Pharmacopeia General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings (USP <800>).

It is the position of the Commission that USP <800> does not require a separate storage room solely for ingredients or products of hazardous drug compounding.

**BACKGROUND:**

In Washington, individuals and facilities licensed by the Commission are required by statute to comply with the standards of the official United States Pharmacopeia (USP) as it applies to compounding of nonsterile and sterile products (RCW 18.64.270(2)). The Commission has interpreted this provision to require individuals and facilities to comply with USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and USP General Chapter <797> - Pharmaceutical Compounding – Sterile Preparations (USP <797>). The Commission has indicated that USP <800> will become required once made official by the USP.

USP published a final version of USP <800> in February 2016. Originally, USP intended USP <800> to have an official date of July 1, 2018. Subsequently, USP has announced its intent to postpone the effective date of USP <800> to December 1, 2019. USP postponed the effective date in order to align the official date of USP <800> with the official date of the revised USP <797>. Amongst other things, the postponement of publication of updates to USP <797> and
USP <800> will be harmonized and ensure a uniform approach to the sterile compounding of hazardous drugs.

The Commission has formalized a policy statement, Number 60 – Regulations of the Handling of Hazardous Drugs, allowing early adoption of USP <800> in Washington for facilities licensed under RCW- chapter 18.64. This was because the Commission felt compliance with USP <800> would ensure patient safety and promote public health, and allow licensed facilities to begin any necessary upgrades.

This interpretation applies both currently to those who are early adopters of USP 800 as well as after the official effective date.

An issue arose over whether USP <800> required a separate storage room for ingredients and products used in hazardous drug compounding. The current USP <797> does have a section titled “Hazardous Drugs as CSPs” but this section does not speak directly to the storage of hazardous drugs. USP <800> states the following regarding the storage of hazardous drugs (HDs):

Antineoplastic HDs requiring manipulation, other than counting or repackaging of final dosage forms, and any HD API [active pharmaceutical ingredient] must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.

Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.¹

USP <800>, 5.2 Storage.

While hazardous drugs must be stored separately from other inventory in a manner to prevent contamination and personnel exposure, a separate storage room may not be necessary. The intent of the language in USP <800> 5.2 Storage is to indicate that certain products used in hazardous drug compounding cannot be stored on the same shelf or exact area as non-hazardous drug compounded sterile preparations (CSPs) and components used to compounding non-hazardous drugs. This is due to potential contamination or personnel exposure.

For example, The National Institute for Occupational Safety and Health (NIOSH) Table 1 drugs used to compound CSPs, must be stored in a negative pressure room (-0.01 to -0.03 w.c.) with a minimum of 12 air changes per hour that is externally vented. This room may be the HD compounding buffer room, or a separate room where only HD drugs are stored. Some examples include bendamustine, cisplatin, cyclophosphamide iv, fluorouracil iv, gemcitabine, irinotecan, methotrexate iv, and pertuzumab.

¹ This paragraph from USP <800> is a “should” statement and is not a requirement.
Oral NIOSH table 1 medications that do not require manipulation, may be stored with non-HD inventory if permitted by entity policy and an assessment of risk is completed. Some examples include everolimus, hydroxyurea oral capsule, imatinib, methotrexate oral tablets.

If the entity has completed an assessment of risk, per USP 800, NIOSH table 2 and 3 medications may be stored with other non-HD inventory if specified in entity policy. Some common examples of medications include:

Table 2: Carbamazepine, cyclosporine, divalproex, estrogen, fosphenytoin, ganciclovir, medroxyprogesterone, mycophenolate, phenytoin, progestins, risperidone, spironolactone, zidovudine.

Table 3: Clonazepam, colchicine, finasteride, fluconazole, gonadotropin, mifepristone, oxytocin, paroxetine, temazepam, testosterone, tretinoin, valproate/valproic acid, voriconazole, warfarin, zoledronic acid.

The most current version of the NIOSH list of antineoplastic and other hazardous drugs should guide facility assessment.

In all cases HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure, in a negative pressure room with a minimum of 12 air changes per hour that is externally vented.

**CONCLUSION:**

The Commission interprets USP <800> language as not requiring a separate storage room solely for hazardous drugs.