Commission SBAR Communication

Agenda Item/Title: Item 4.1 d. Applicability of USP 800

Date SBAR Communication Prepared: July 24, 2019

Reviewer: Tracy West

Link to Action Plan:
- Action
- Information
- Follow-up
- Report only

Situation:
The Commission needs to discuss where and when USP 800 is required and enforceable.

This analysis may change depending on the definition of compounding analysis provided by Christopher Gerard, AAG as part of Agenda Item 4.1a.

Background:

RCW 18.64.270(2) requires those credentialed by the Commission who are engaged in compounding to be in compliance with USP chapters related to compounding standards.

Over the last two years the USP Expert Committee has been in the process of updating and making revising chapters related to the USP chapters on compounding, these include:

- USP chapter <795> - Nonsterile Compounding (revision published 6/1/19)
- USP chapter <797> - Sterile Compounding (revision published 6/1/19)
- USP chapter <800> - Handling of Hazardous Drugs (revision published 2/1/16)
- USP chapter <825> - Radiopharmaceutical Compounding (revision published 6/1/19)

Revisions were published to USP <800> in February 2016, but had an effective date of July 28, 2018. During that time USP <795> and <797> were out for public comment, and based on the number of comments received the USP Expert Committee pulled back the proposed revisions and began to rework them. This resulted in USP delaying the effective date of USP 800 to December 1, 2019 to coincide with the publishing of the updates to USP <795> and <797>.

USP has published FAQs on USP <800>, two of which are applicable to this discussion.

8. *UPDATED* What is the compendial status of <800>?

From a compendial standpoint, a USP general chapter numbered below <1000> becomes applicable and compendially required through reference in General Notices, a monograph, or another applicable general chapter numbered below <1000>.

General Chapters <795> and <797> are made applicable and compendially required through reference in General Notices (See General Notices 3.10.30). In addition, <795> and <797> are made applicable and compendially required for specific formulations where there is a USP Compounded Preparation monograph that makes reference to these chapters.
General Chapters <795> and <797> have been revised to include cross-references to <800>. These cross-references make <800> an applicable general chapter for facilities that are compendially required to implement <795> and <797>. For hazardous drugs, this means only when a licensed pharmacist or physician is "compounding" (as that term is defined in <795> and <797>) would <795>/<797> and <800> be applicable and compendially required.

USP plays no role in enforcement, and thus, state and other regulators may make their own determinations regarding the applicability and enforceability of <800> to entities within their jurisdiction. It is possible for states and other regulators to require broader implementation of, and compliance with, <800>, i.e., for facilities engaged in activities that are beyond the scope of nonsterile and sterile compounding covered by <795> and <797>.

9. *UPDATED* Is the chapter relevant to the administration of HDs and preparation of conventionally manufactured sterile products per approved labeling?

From a scientific standpoint, the principles of <800> are broadly applicable to hazardous drug handling activities across all facility types. USP encourages the widespread adoption and use of <800> across all healthcare settings.

General Chapter <800> is made applicable and compendially required through references in General Chapter <797> and <795>. The requirements in <800> would be applicable and compendially required only to the extent to which USP General Chapters <795> and <797> apply. For hazardous drugs, this means only when a licensed pharmacist or physician is "compounding" (as that term is defined in <795> and <797>) would <800> be applicable and compendially required. Since administration and preparation of conventionally manufactured sterile products per approved labeling (as described in <797>) is out of scope of <797>, General Chapter <800> is not applicable or compendially required in these contexts.

USP plays no role in enforcement, and thus, state and other regulators may make their own determinations regarding the applicability and enforceability of <800> to entities within their jurisdiction. It is possible for states and other regulators to require broader implementation of, and compliance with, <800>, i.e., for facilities engaged in activities that are beyond the scope of nonsterile and sterile compounding covered by <795> and <797>.

[Highlighting Added.]

**Assessment:**
Staff have not had the opportunity to do a more thorough analysis on the above questions and how they impact, if at all, the Commission’s enforceability options in light of RCW 18.64.270(2).

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It would appear from the FAQs and previous interpretations of RCW 18.64.270(2) that USP <800> would be a required standard for all of the Commission’s licensees who are subject to the provisions chapter 18.64 RCW. Most likely this would not apply to long-term care facilities, or physician offices, since they are not regulated by the Commission. Those facilities would likely need to comply with the Department of Labor and Industries Hazardous Drug Handling rules.

Recommendation:
Allow staff to work with Christopher Gerard, AAG to determine if a more thorough analysis or if USP <800> is applicable via the requirement to meet USP standards as stated in RCW 18.64.270(2).

Follow-up Action: N/A