California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Compounding Committee Report
November 5, 2019

Maria Serpa, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member

1. Call to Order and Establishment of Quorum

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings*
   **Note: The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a)*

3. Discussion and Consideration of Draft Policy Statement Regarding Applicability of Board Compounding Regulations and USP Compounding Chapters While Pending Appeals Before USP

   Attachment 1

   Background
   On September 23, 2019, USP announced a delay in the official date of the of the revised Chapters 795 and 797 and the new Chapter 825 until further notices. The delay results from appeals received on certain provisions of the respective Chapters.

   Since the beginning of the year the committee has dedicated several meetings to education on the proposed revised and new chapters. Following education, the committee transitioned its work to evaluating regulations necessary to clarify, make more specific and necessary to ensure safe processes consistent with the board's mandate.

   For Committee Consideration
   In light of the delay in the official date of the Chapters, it is appropriate for the committee to discuss what if any actions the board should consider. During the meeting the committee will consider a draft policy statement intended to provide clarification to the board's regulated public about the board's intentions to regulate pharmacy compounding of drug preparations during the appeal process.

   Attachment 1 includes a copy of a draft policy statement and the USP notification.

4. Discussion and Consideration of Timing of Formal Rulemaking for Proposed Regulations Relating to Pharmaceutical Compounding of Nonsterile Preparations

   Background
   On July 11, 2019, the committee approved proposed regulations to repeal and add new CCR sections 1735 through 1735.15 relating to Nonsterile Preparations, including sections. The board considered the committee's recommendation as part of its July 2019 meeting. The board voted to initiate a rulemaking related to Nonsterile Preparations.

   For Committee Consideration
   Following discussion on the draft policy statement, it may be appropriate for the committee to consider the timing of the rulemaking to establish new standards for the compounding of nonsterile preparations. As indicated on the meeting agenda, discussion will be limited to the timing of the initiation of the rulemaking and will not include discussion of the proposed regulation language.

5. Discussion of Timing of Committee's Prior Recommendation to Initiate the Formal Rulemaking Process for Proposed Regulations Relating to Pharmaceutical Compounding of Sterile Preparations

   Background
   During its September 5, 2019 and September 25, 2019, meetings, members reviewed proposed regulations necessary for patient safety related to pharmaceutical compounding of sterile preparations. These proposed regulations are predicated on the newly revised USP 797 and other relevant state and federal law. Following its discussion, the committee voted to recommend initiation of a rulemaking to rename Article 7 Sterile Compounding and Repeal Sections 1751-1751.10 and replace with Article 7 Sterile Compounding in Pharmacies including the addition of Sections 1751-1751.21.

   For Committee Consideration
   Similar to the previous agenda item, discussion on this topic is limited to the timing of the committee's recommendation to initiate the formal rulemaking.

6. Future Committee Meeting Dates

   Future committee meeting dates will be determined following USP updates.

7. Adjournment

Attachment 1

USP General Chapters <795>, <797>, <800>, and <825>

Type of Posting: Notice of Intent to Revise
Posting Date: 23–Sep–2019
Official Date December 1, 2019; TBD
Expert Committee: Compounding, Chemical Medicines Monographs 4

On June 1, 2019, USP published revisions to <795> *Pharmaceutical Compounding – Nonsterile Preparations* and <797> *Pharmaceutical Compounding – Sterile Preparations*, as well as a new chapter <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>.

In accordance with USP's Bylaws, the responsible Expert Committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see Decisions on Appeals to USP <795> and <797> and <825>). In accordance with USP's formal appeals process, stakeholders who submitted appeals on the compounding chapters have requested further review by an appointed Panel.

USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, **USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice**. In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section *Radiopharmaceuticals as CSPs* will remain official. The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.

General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

USP plays no role in enforcement. State and other regulators may make their own determinations regarding the enforceability of <800>. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process. For any questions, please contact the Healthcare Quality & Safety Team at CompoundingSL@usp.org.

In light of the USP's September 23, 2019 announcement regarding the appeals and resulting postponement of the official dates of the revised USP Chapters 795 and 797 and the new USP Chapter 825, the California State Board of Pharmacy (board) wishes to ensure that stakeholders have a clear understanding of the legal requirements pharmacies must comply with to compound drug preparations.

At minimum, all pharmacies must adhere to all relevant sections of Pharmacy Law and regulation, including but not limited to the board's current regulations California Code of Regulations, title 16, sections 1735 et. seq, 1751 et. seq, and 1708.3-1708.5. Further, effective January 1, 2020, all pharmacies must adhere to current USP Chapters relating to compounding, including Chapters 795 and 797.

The board notes that while USP has indicated that Chapter 800 is informational while it reviews the appeals of related compounding chapters, the board's current regulations on compounding hazardous drug preparations remain in effect. Like USP, the board encourages utilization of 800 in the interest of advancing public health. Waivers previously granted to allow for physical construction or alteration to a facility pursuant to California Code of Regulations 1735.6 will not be extended and sunset on December 1, 2019.

Prior to September 23, 2019, the board voted to initiate a rulemaking process to effectuate proposed changes to regulations for pharmaceutical compounding of nonsterile preparations. At this time, the board will delay initiation of the formal rulemaking process until additional information is available from the USP.

Although the board's compounding committee had completed its review of proposed regulations for pharmaceutical compounding of sterile preparations, the board will delay proceeding with any regulation changes until additional information is available from the USP.

The board encourages its licensees to continue efforts to transition to proposed USP requirements that ensure the safety and efficacy of compounded drug preparations and patient safety. The board will continue to communicate with stakeholders as information becomes available.