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Compounding Requirements Pending USP Appeals

In light of USP's September 23, 2019, announcement regarding the appeals and postponement of the official dates of the revised Chapters 795 and 797 and the new Chapter 825, the California State Board of Pharmacy (board) wishes to ensure stakeholders have a clear understanding of the legal requirements for pharmacies compounding 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, in addition to the board's compounding regulations, all pharmacies must adhere to current USP Chapters relating to compounding, including Chapters 795 and 797.

Although USP has indicated that Chapter 800 is informational while USP 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 Chapter 800 in the interest of advancing public health.

Waivers previously granted to allow for physical construction or alteration of a facility pursuant to California Code of Regulations, title 16, sections 1735.6 or 1751.4 will not be extended and will sunset on December 1, 2019. While the USP appeals are under consideration, where physical construction or alteration is not yet complete, the board will consider mitigation, including a licensee's efforts to achieve compliance.

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.

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