

5/7/20

Compounding Requirements Following USP Appeal Decisions

In light of USP's March 12, 2020, final decision on appeals of the proposed revised Chapters <795> and <797> and the new Chapter <825>, the California State Board of Pharmacy (Board) provides its stakeholders with this current status of the legal requirements for pharmacies compounding drug preparations.

As the Board reads the decisions, some of the appeals to Chapters <795> and <797> were granted, sending the chapters back to the committee for further discussion. Accordingly, the current chapters of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations, including but not limited to the Board's current regulations – title 16, California Code of Regulations, section 1735 et. seq. (Article 4.5, Compounding); section 1751 et. seq. (Article 7, Sterile Compounding); and section 1708.3 to section 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant sections.

Although USP has indicated that Chapter <800> is informational and not compendially applicable unless and until Chapters <795> and <797> are revised and reference Chapter <800>, 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.

The Board's Compounding Committee has been reintegrated into the Board's Enforcement Committee. At this time, the Board does not intend to pursue changes to the current regulations governing compounded preparations. The Board will continue to communicate with stakeholders as information becomes available.

This is a link to the Appeals Panel decisions on USP Chapters <795>, <797>, and <825>:
<https://www.usp.org/sites/default/files/usp/document/our-work/compounding/decisions-appeals-fs.pdf>.

The Board reminds licensees that in response to the COVID-19 pandemic, waivers to provisions of Pharmacy Law have been granted. Information regarding the waivers is provided on the Board's website, www.pharmacy.ca.gov.

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