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

To: Board Members

Subject: Agenda Item II. Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, Repeal of Sections 1708.3, 1708.4, 1735 et seq and 1751 et seq and Addition of Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq Related to Compounded Drug Preparations, Hazardous Drugs, and Radiopharmaceuticals, and Review of Comments Received to Third Modified Text During the 15-Day Comment Period

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Relevant Law:

There are a number of provisions of both state and federal law that govern the practice of pharmacy, including provisions in Pharmacy Law. The rulemaking documents, which have been available to the public, detail many of the provisions. Provided below are some of the provisions with broad applicability.

Section 503A of the federal Food, Drug, and Cosmetic Act (FDCA) describes conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from certain provisions of the FDCA, i.e., sections 505, 502(f)(1), and 501(a)(2)(B). The exemptions concern provisions related to current good manufacturing practices, labeling of drugs with adequate directions for use, and the new drug approval process. A drug product intended for use in humans that is compounded in compliance with section 503A is exempt from these specified requirements; however, all other applicable provisions of the FDCA remain in effect for compounded drugs, even if the conditions of section 503A are met.

Section 503A(b)(1)(A)(i) provides that a drug product may be compounded if the licensed pharmacist or licensed physician compounds the drug product using bulk substances that:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
3. If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.

21 C.F.R. Section 216.23(a) includes the bulk drug substances that can be used

to compound drugs products pursuant to section 503A(b)(1)(A)(i)(III).

To gain a full understanding of all of the requirements, pharmacists and others should read section 503A and other applicable provisions of the FDCA. **Note**: A presentation covering the federal requirements was provided during the January 2023 Enforcement and Compounding Committee meeting. Meeting slides are available here and the livestream of the meeting is available here. More recently, a presentation was provided to the Board during the November 6-7, 2024, Board meeting. The slides are available here and the livestream is available here.

Business and Professions Code (BPC) section 4126.8 generally provides that the compounding of drug preparations by a pharmacy for furnishing, distribution, or use in California shall be consistent with the standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary. (**Note**: Federal law imposes a similar requirement for compliance with USP.)

BPC section 4127(c) requires the Board to review any formal revisions to General Chapter 797 of the USP, relating to the compounding of sterile preparations, not later than 90 days after the revisions become official, to determine whether amendments are necessary for regulations adopted by the Board.

BPC section 4342 generally provides the Board with the authority to institute any action or actions necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to the quality and strength provided in the latest version of the USP, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Health and Safety Code sections 109875 – 111929.4).

Background:

The Board's first regulations related to compounding became effective in 1986. Over the years, the regulations have been expanded and amended.

The Board's most recent efforts to update its regulations began in 2019, when, in response to proposed changes to the USP, the Board initiated review of its compounding regulations through the Board's Enforcement and Compounding Committee. A series of public meetings were held and proposed language was discussed in a collaborative manner with stakeholders. In response to subsequent appeals to the provisions contained within the proposed USP changes, the Board suspended its efforts while the USP considered the appeals. On November 5, 2019, in light of the delays with USP, the Committee considered a Draft Policy Statement to provide stakeholders with guidance on the applicability of the Board's compounding regulations and USP compounding chapters while appeals were pending before the USP Committee.

Following the finalization of the USP Chapters, the Board, again through the Enforcement and Compounding Committee, resumed its efforts to evaluate, and where necessary update, its compounding regulations. Again, a series of meetings were held with significant participation and stakeholder comments. Proposed changes include restructuring of the Board's regulations to align with the USP Chapters, elimination and clarification of requirements, and addition of new requirements.

At the April 2023 Board meeting, the Board approved proposed regulation text that would amend the Board's regulations regarding compounded drug preparations to implement, clarify, or make more specific requirements related to the United States Pharmacopeia-National Formulary, Chapter <795> for nonsterile compounding, Chapter <797> for sterile compounding, Chapter <800> related to hazardous drugs – handling in healthcare settings, and Chapter <825> related to radiopharmaceuticals – preparation, compounding, dispensing, and repackaging. Federal law and USP standards are not repeated in the proposed language. Understanding that the USP Chapters became effective on November 1, 2023, and the Board's proposed regulations would not be effective, the Board released an updated Policy Statement on September 12, 2023, providing stakeholders with additional guidance.

As required by the Administrative Procedure Act, the proposed text that the Board had approved was published and distributed to interested parties for a 45-day comment period on April 19, 2024, which ended on June 3, 2024. Additionally, Board staff held a regulation hearing on June 18, 2024, to accept oral comments. Numerous comments were received.

During the July 31 – August 1, 2024, Board meeting, members considered the comments received and Board staff recommended changes to the text, which were dated 7/19/2024, based on those comments. The Board dedicated a significant amount of time to the discussion and received extensive additional public comment. Ultimately, the Board delegated authority for Members Serpa and Barker to evaluate the information provided at the meeting and, consistent with the Board's discussion and direction, develop further recommended changes to the 7/19/2024 proposed modified text.

During the September 12, 2024, Board meeting, members resumed consideration of the proposed modified text, including additional changes recommended by Members Serpa and Barker, consistent with the Board's discussion and direction. The Board again received significant public comment. Based on the comments received, the Board determined that additional education was necessary before it proceeded with determining the next steps.

During the November 6-7, 2024, Board meeting, members resumed

consideration of the proposed modified text, which included the additional changes recommended by Members Serpa and Barker. Following extensive discussion and public comment, members, among other actions, approved the recommended modified regulation text for a 30-day comment period.

On November 8, 2024, the proposed modified text that the Board had approved was posted and distributed to interested parties for a 30-day comment period, which ended on December 9, 2024. Comments were received in response to this comment period.

During its January 8, 2025, Board meeting, members considered comments received during the 30-day comment period and additional changes recommended by Members Serpa and Barker and staff. Following extensive discussion and public comment, members, among other actions, approved a second modified regulation text for a 15-day comment period.

On January 10, 2025, the proposed second modified text that the Board approved was posted and distributed to interested parties for a 15-day comment period, which ended on January 27, 2025. Comments were received during this comment period. Following extensive discussion and public comment, members approved a third modified regulation text for a second 15-day comment period during the Board's February 5-6, 2025, Board Meeting.

On February 6, 2025, the third modified text was released. The comment period ended February 21, 2025.

Summary of Changes

During the meeting, members will have the opportunity to consider the comments received in response to the second 15-day comment period and changes being recommended to the proposed text based on the comments received. To assist members and interested parties in understanding the scope of the recommended changes, below is summary information for the various sections of the proposed regulations highlighting some of the recommended substantive changes.

Sterile Compounding

- Clarifying the reporting requirements when a failure results in a transition to immediate use provisions.
- Changing the requirements for compounding using Category 1 bulk drugs substances that replace the current approach with an approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and national standards.

Hazardous Drugs (HDs)

- Removing provisions related to changing gloves between each different HD preparations.

Attached to this memo are the following:

1. The recommended fourth modified text, including the changes recommended by Members Serpa and Barker consistent with delegated authority (dated 2/27/25).
2. Comments received during the second 15-day comment period.
3. The original proposed text (dated 3/24/24)
4. The modified text (dated 8/29/2024)
5. The second modified text (dated 1/9/2025)
6. The third modified text (dated 1/30/2025)
7. Correspondence from Reji Varghese, Executive Director, Medical Board of California.

Historical information considered during the November 6-7, 2024, Board meeting is available here.

At this Meeting:

During the meeting, members will have the opportunity to review the comments received during the 15-day comment period for the third modified text, approve staff recommended responses to comments received, and consider recommended fourth modified text for a 15-day public comment period.

Possible Motion Language:

1. Accept the Board staff recommended responses to comments to the third modified text received during the 15-day comment period as the responses of the Board [either "as presented" or "consistent with the Board's discussion"].
2. Approve the recommended fourth modified text [either "dated 2.27.2025 or "as directed by the Board"] for a 15-day comment period.
3. Additionally, should additional comments be received during the comment period, delegate to Members Serpa and Barker authority to review the comments with staff to offer recommendations to the Board for consideration at a future meeting.