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

To: Board Members

Subject: Agenda Item VI. 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, Including Review of Any Comments Received During the 45-Day Comment Period and Regulation Hearing

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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 detail many of the provisions. Provided below are some of the provisions with broad applicability.

Section 503A, provides exemptions from certain provisions under the federal Food, Drug and Cosmetic Act (FDCA), including Section 505, 502(f), and 501(a)(2)(B). **Note**: A presentation of the federal requirements was provided during the January 2023 Enforcement and Compounding Committee. Meeting slides are available here and the livestream of the meeting is available here.

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

BPC 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 4342 generally provides the Board with the authority to institute any action or actions as necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests of the USP or that violate any provision of the Sherman Food, Drug, and Cosmetic Act.

Background:

Beginning in 2019, in response to proposed changes to the USP, through the Board's Enforcement and Compounding Committee, the Board initiated review of its compounding regulations. A series of public meetings were held and

proposed language was discussed in a collaborative manner with stakeholders. In response to subsequent appeals to provisions contained within proposed USP changes, the Board suspended its efforts while appeals where considered by the USP. 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 board compounding regulations and USP compounding chapters while appeals were pending before the USP Committee.

Following 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 comments from stakeholders.

At the April 2023, Board meeting, the Board approved proposed regulation text dated 3/24/24 related to Compounded Drug Preparations. This proposal amends 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 yet 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, Board staff released the proposed text for the 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 30 – August 1, 2024 Board Meeting, members considered the comments received and recommended changes to the text based on those comments. The Board dedicated a significant amount of time to the discussion and received 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 modified text dated 7/19/24.

<u>Summary of Changes</u>

During the meeting members will have the opportunity to resume discussion on recommended changes to the proposed regulation text. To assist members and interested parties in understanding the scope of the changes, below are

summary comments for the various sections.

Nonsterile Compounding

- Clarifying the provisions for compounding when a pharmacist determines a clinical need exists for a patient.
- Clarifying language surrounding requirements for reporting of potential conditions that could result in contamination of the compounding environment.
- Extending the time period to review and report complaints of potential compounding quality issues to the Board.
- Nonsubstantive changes to the language to address grammatical issues and to improve clarity of the language.

Sterile Compounding

- Provide authority for a health care facility licensed pursuant to Health and Safety Code 1250 to compound "essentially a copy" of a product under specified conditions.
- Clarifying the provisions for compounding when a pharmacist determines a clinical need exists for a patient.
- Extending the period of time for a person who has failed specified ongoing training and competency to continue performing specified functions.
- Removal of requirement for identification to the genus level, regardless of CFU count, to trend for growth of microorganisms.
- Extending the time period to review and report complaints of potential compounding quality issues to the Board.
- Updating the provisions for compounding using a bulk drug substance published in the 503A Category I bulk drug substances list.
- Nonsubstantive changes to the language to address grammatical issues and to improve clarity of the language and to include the titles of referenced USP Chapters.

Hazardous Drugs

- Article will only apply to hazardous drug compounding and in some instances performing "other manipulations" included in Table 1 of the Chapter of antineoplastic HDs. (e.g. HD/Antineoplastic Tablet splitting or crushing)
- Nonsubstantive changes necessary to implement the changes note in the prior bullet.

Radiopharmaceuticals

- Removal of requirement for identification to the genus level, regardless of CFU count, to trend for growth of microorganisms.
- Nonsubstantive change to clarify requirement related to facility and engineering controls related to compounding of radiopharmaceuticals and to improve clarify of the language.

Attached following this memo are the following:

1. The updated recommended modified text, including the changes recommended by Members Serpa and Barker consistent with the delegated authority. (dated 8/29/24)
2. The updated recommended modified text with changes highlighted in yellow to illustrate the changes after July 31-Aug 1 Board meeting.
3. Supplemental board staff prepared summarized comments with recommendations incorporating the changes reflected in updated recommended modified text (dated 8/31/24)
4. Board staff prepared summarized comments with recommendations from the 45-day comment period and hearing.
5. Board staff recommended modified text (dated 7/19/24) following the 45-day comment period and hearing.
6. Comments received during the 45-day comment period. (Comments from the regulation hearing are available to hear at the following website: https://youtu.be/VDderHcJsEY)
7. The original proposed text (dated 3/24/24) released for the 45-day public comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue.

Possible Motion Language:

1. Accept the Board staff recommended initial comment responses (from 45-day comment period and hearing) and updated supplemental responses as provided.
2. Approved the recommended updated modified regulation text [either "dated 8/xx/24) as presented" 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 present recommended changes to the Board in response to the additional comments.
4. Further, should no adverse comments be received during the comment period, authorize the Executive Officer to take all steps necessary adopt the proposed regulation at Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq and complete the rulemaking process. Finally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.