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

COMPOUNDING COMMITTEE
DRAFT MEETING MINUTES

DATE: November 5, 2019

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd.,1st Floor Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chairperson
Allen Schaad, Licensee Member, Vice Chairperson
Greg Lippe, Public Member, Acting President

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Laura Freedman, DCA Staff Counsel
Norine Marks, DCA Staff Counsel
Kristina Jarvis, Deputy Attorney General
Debbie Damoth, Administration Manager

1. **Call to Order and Establishment of Quorum**

   Chairperson Serpa called the meeting to order at 8:50 a.m. Board members present at the meeting were: Allen Schaad, Greg Lippe and Maria Serpa. A quorum was established.

2. **Public Comment for Items not on the Agenda, Matters for Future Meetings**

   There were no comments from the committee or the public.

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

   Dr. Serpa provided background on the committee's actions during past meetings. She noted the committee determined, and the full board agreed, that regulations mirror the structure of the USP chapters, including separate requirements for the various types of compounding preparations. The committee completed the review of proposed regulations relating to nonsterile preparations, that may be necessary to implement, clarify, or make more specific requirements related to USP Chapter 795 as well as to ensure safe compounding processes consistent with the board's consumer protection mandate. Following the committee's work, the board considered the proposal and voted to initiate

the rulemaking process as part of its July 2019 meeting. The rulemaking package was submitted to DCA to begin its review.

Dr. Serpa continued, during subsequent meetings the committee focused on proposed regulations for the compounding of sterile preparations necessary to implement, clarify, or make more specific requirements related to USP 797, consistent with the board's consumer protection mandate. During the September 24, 2019, meeting, the committee finalized its review of the proposed regulations and voted to recommend initiating a rulemaking on proposed regulations relating to sterile preparations.

Dr. Serpa reported on September 23, 2019, USP announced a delay in the official date of revised Chapters 795, 797 and new Chapter 800 until further notice. As indicated in the meeting materials, the delay results from appeals received on certain provisions of the respective Chapters.

Dr. Serpa noted she believed it was appropriate to consider a policy statement to provide guidance to the board's regulated public about the applicability of compounding regulations. She noted, included in the meeting materials is a draft statement. Dr. Serpa highlighted that as part of the draft statement she recommended the board delay initiation of the formal rulemaking process for regulations for nonsterile preparations and with any regulation changes related to the compounding of sterile preparations. The draft statement also advises licensees about the compounding requirements all pharmacies must adhere.

The committee heard comments inquiring from the committee if there will now be a conflict between current board regulations and the 2008 USP <797> relative to sterile compounding. Commenters explained to the committee 2008 USP <797> currently allows for low volume hazardous drugs are able to be made in positive pressure but current board regulations say all hazardous drugs need to be made in negative pressure. The board had previously approved construction waivers to allow for the construction of the negative pressure rooms but all waivers will expire Dec. 1, 2019.

Ms. Sodergren provided the requirements in the board regulations have been in effect for several years and waivers were granted in order to allow licensees to achieve compliance. She explained the board could provide staff with policy direction and give guidance to staff to assess each on a case by case basis. This would allow for action to be taken that is appropriate based on the fact pattern and factoring in mitigation referenced in pharmacy law in terms of assessing violations.

The commenters were advised the board would not be extending waivers but would apply enforcement discretion when assessing where a facility was in the process of the construction for negative pressure rooms. Considering factors would include steps made by facilities within the documented plans. Dr. Serpa noted a time frame should be included and could be based on when USP is finalized.

The committee entertained a question as to conflict between current USP and board regulations with the passing of AB 973 (Irwin, Chapter 184, Statutes of 2019) that as of January 1, 2020, all compounding must be consistent with versions of USP. The commenter was advised the board's regulations remain in effect and this was addressed in the second paragraph of the draft policy statement.

The committee received comment that a statute supersedes regulation. DCA Counsel Freedman advised due to the language of the law, that is not an issue. It does not undermine or repeal the board's existing regulations but creates an additional layer and to the extent that the board's regulations are more stringent, those will continue to apply.

Motion: Accept the draft policy statement to present to the board and to include the amendments discussed about enforcement discretion to be determined and the addition of California regulations to the second paragraph.

M/S: Lippe/Schaad

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Schaad	Support			
Serpa	Support			
Lippe	Support			

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

Dr. Serpa advised the committee consistent with the policy statement, it is appropriate to recommend to the board a delay in the initiation of this rulemaking.

Motion: Recommend to the board to hold the formal rulemaking process previously approved by the board relating to pharmaceutical compounding of nonsterile preparations.

M/S: Lippe/Schaad

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Schaad	Support			
Serpa	Support			
Lippe	Support			

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

Dr. Serpa proposed the committee discuss the timing of the committee's prior recommendation to initiate a formal rulemaking process for proposed regulations related to sterile preparations.

Motion: Recommend to the board to not initiate the formal rulemaking process relating to pharmaceutical compounding of sterile preparations.

M/S: Lippe/Schaad

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Schaad	Support			
Serpa	Support			
Lippe	Support			

6. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting will be established as USP information becomes available and posted on the board's website when determined.

7. Adjournment

Chairperson Serpa adjourned the meeting at 9:23 a.m.