



**ENFORCEMENT AND COMPOUNDING COMMITTEE
 MEETING MINUTES**

DATE: January 18, 2022

LOCATION: Teleconference Public Committee Meeting
 Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member Chair
 Jig Patel, Licensee Member Vice Chair
 Seung Oh, Licensee Member
 Debbie Veale, Licensee Member

COMMITTEE MEMBERS ABSENT: Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Maria Serpa called the meeting to order at 9:01 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency.

The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Jignesh Patel, Seung Oh, Debbie Veale, and Maria Serpa. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were provided.

III. Approval of October 20, 2021, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes.

Motion: Approve the October 20, 2021, Committee Meeting minutes as presented.

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment; however, none were offered.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Oh	Support
Patel	Support
Sanchez	Not present
Serpa	Support
Veale	Support

IV. Discussion and Consideration of Board's Disciplinary Guidelines

Chairperson Serpa referenced the meeting materials which provided background information including some of the relevant provisions of law and reminded members that as part of the July 2021 meeting, the committee requested that staff complete a review and provide recommendations for changes to the Disciplinary Guidelines. The proposed changes are reflected in the guidelines in the meeting materials.

Chairperson Serpa reviewed types of changes being recommended as detailed in the meeting materials and displayed on the meeting slide. Dr. Serpa acknowledged staff and counsel for their work.

Chairperson Serpa noted agreement with the proposed changes and noted an additional change in language be inclusive of all USP sections referring to a designated individual responsible for compounding and not limit just to sterile compounding in USP 797 when referring to optional language.

Member Oh requested clarification on several elements of the Disciplinary Guidelines. Members also discussed provisions related to reinstatement of licensure versus terms for a licensee placed on probation. Members considered if the current categories for discipline related to business licenses were appropriate. The committee carefully considered several changes being recommended as well as the current provisions.

The committee agreed that the summary paragraph provided under “Terms of Probation – Individual Licensees (page 5) and “Terms of Probation – Premises” (Page 41) should be edited to remove the first two sentences. Further, the committee agreed that a change to the optional language under Term 8 – “Restrictions on Supervision and Oversight of Licensed Facilities” (page 18) should be amended to expand to include all compounding.

Motion: Recommend initiate of a rulemaking to amend CCR section 1760 and the Disciplinary Guidelines incorporated by reference, as presented with addition of: the summary paragraph provided under “Terms of Probation – Individual Licensees (page 5) and “Terms of Probation – Premises” (Page 41) should be edited to remove the first two sentences and change the optional language under Term 8 – “Restrictions on Supervision and Oversight of Licensed Facilities” (page 18) should be amended to expand to include all USP compounding. Authorize the Executive Officer with the Chairperson to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adoptive proposed regulation at section 1760 as presented.

Title 16. Board of Pharmacy Proposed Text

Proposed changes to current regulation text are indicated with ~~single strikethrough~~ for deletions and single underline for additions.

Amend Sections 1760 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled “Disciplinary Guidelines” (Rev. ~~2/2017~~ 1/2022), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation -the presence of mitigating factors; the age of the case; evidentiary problems.

Note: Authority cited: Sections 315, 315.2, 315.4 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4 and 4300-4313, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

[Note: A copy of the draft referenced Disciplinary Guidelines are attached to the minutes.]

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment.

Public comment indicated that Category 1 calls for revocation, stayed and a minimum period of probation. The commenter indicated that some of the types of violations included in categories could be handled through citations or corrections and indicated that it is way too harsh. The commenter also suggested that a Letter of Public Reproval should be used more often.

Dr. Serpa reminded everyone that the Disciplinary Guidelines are designed to ensure public safety.

Public comment also requested that the committee consider if the guidelines are appropriate for a standard of care and suggested that the Board uses uneven discipline.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Oh	Support
Patel	Support
Sanchez	Not present
Serpa	Support
Veale	Support

V. Discussion and Consideration of the Draft Frequently Asked Questions Developed to Discuss Requirements for Outsourcing Facilities Providing Patient Specific Prescriptions

Chairperson Serpa reminded members that as part of the October 2021 meeting, members discussed implementation of several provisions contained in Assembly Bill 1533, including provisions to allow for a California licensed outsourcing facility to dispense patient specific prescriptions. As part of that discussion, the committee noted the need to develop educational materials to assist entities with understanding the relevant provisions of Pharmacy Law.

Members considered the draft FAQs.

Motion: Approve FAQs related to patient specific prescriptions dispensed by a California licensed outsourcing facility within or into California

[Note: A copy of the draft referenced FAQs are attached to the minutes.]

M/S: Oh/Veale

Members of the public were provided with an opportunity to provide public comment.

Public comment indicated that the document should be amended to include questions about security and asked if only a pharmacist can open and close a pharmacy and separation of GMP compounding activities.

Chairperson Serpa clarified the FAQs were specific to patient-specific prescriptions and not to the licensure category for outsourcing facilities. She stated this is just one function of the outsourcing facility.

Dr. Oh inquired if an outsourcing facility providing individual patient prescriptions would need to complete different self-assessments. Ms. Sodergren indicated staff are working on unique self-assessments but they have not been brought to the committee or Board.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Oh	Support
Patel	Support
Sanchez	Not present
Serpa	Support
Veale	Support

VI. Discussion and Consideration of Senate Bill 311 (Hueso, Chapter 384, Statutes of 2021) Compassionate Access to Medical Cannabis Act or Ryan’s Law

Dr. Serpa reminded members of the previous discussion on the measure and conflicts with the measure itself as well as conflicts with the stated intent of the measure as it relates to the handling and use of patient-provided medicinal cannabis within a hospital.

Chairperson Serpa also advised members of the author's intent to pursue amendments to clarify the intent of the measure as included in the letter to the Senate Journal and reference the letter in the meeting materials.

Dr. Serpa reminded members that the issue of this legislation goes well beyond the Board's jurisdiction and conveyed an understanding of the concerns of patients and the licensed public and the need for additional information. The Board continues to advocate for education on the proper and safe use of medications and encourages individuals and organizations to continue to provide ongoing education on these types of topics. Dr. Serpa noted that if there are specific legislative concerns, individuals should contact the author's office and if needed be brought to the Legislation and Regulation Committee for consideration.

Members noted agreement with the comments made by Chair Serpa.

Members of the public were provided with the opportunity to provide public comment.

Comments from the public requested that the Board release information about enforcement of the provisions.

Members noted the concerns of the public and recommended concerns be shared with California Department of Public Health.

The meeting was in recess from 10:15 to 10:30. Roll call was taken upon resumption of the meeting. Members present: Jignesh Patel, Seung Oh, Debbie Veale, and Maria Serpa.

VII. Discussion and Consideration of Self-Assessment Forms

Chairperson Serpa remarked that in response to changes in Pharmacy Law, the Board must update the various self-assessment forms. The forms provide licensees with an opportunity to self-assess for compliance with provisions of Pharmacy Law. Dr. Serpa reminded members that the Communication and Public Education Committee is overseeing the development of alternative ways to complete the self-assessments.

Chairperson Serpa directed everyone to the draft versions of the updated forms included in the meeting materials and highlighted the process to formally incorporate the changes of the form into the law, rulemaking for each form is required. Dr. Serpa noted there are several rulemakings for previous changes to these forms already in process to incorporate changes from prior years, and discussion should focus on the newly added changes.

Compounding Self-Assessment (17M-39)

Dr. Serpa referenced the slide displayed that provides the general area of amendment for this form, noting the changes are identified with underlined text and found in section 2.13 and 2.14. These changes include the provisions incorporated in the Board's Sunset Bill, relating to renewal requirements and FDA requirements for compounding for interstate distribution.

Members noted agreement with the proposed changes.

Motion: Recommend approval of the proposed amendments to Compounding Self-Assessment, form 17M-39 and incorporate the proposed amendments into the rulemaking package currently undergoing pre-notice review. Authorize the Chair and Executive Officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency). If no adverse comments are received during the 45-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking, make any non-substantive changes to the package, and adopt Compounding Self-Assessment, form 17M-39, as noticed for public comment.

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment; however, none were offered.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Oh	Support
Patel	Support
Sanchez	Not present
Serpa	Support
Veale	Support

Chairperson Serpa noted that the next three self-assessments were all currently undergoing rulemaking and would be discussed individually followed by a consolidated motion if appropriate.

Community Pharmacy/Hospital Outpatient Self-Assessment (17M-13)

Dr. Serpa referenced summary information displayed on the slide regarding the recommended changes noting that the slide cross referenced sections of the form. The newly added language is displayed with a wavy line in the form itself in the meeting materials.

Chairperson Serpa stated that the changes appeared appropriate.

Member Veale suggested amending the language in Section 6.8 to include the word “only” to ensure consistency with other provisions of the section. Members agreed that such a change would be nonsubstantive.

Hospital Self-Assessment (17M-14)

Dr. Serpa stated that the summary newly added changes were displayed on the slide and noted her agreement with the proposed changes. No additional comments were offered by members.

Wholesaler Self-Assessment (17M-26)

Chairperson Serpa indicated that a summary of newly added changes was again displayed on the slide, with reference to the specific areas of the form. Dr. Serpa again stated agreement with the proposed changes. No additional comments were offered by members.

Motion: Recommend approval of the proposed amendments to self-assessment

forms 17M-13, 17M-14, and 17M-26. Authorize the Chair and Executive Officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency) and notice the proposed amendments for a 15-day comment period. If no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking, make any non-substantive changes to the package, and adopt self-assessment forms 17M-13, 17M-14, and 17M-26 as noticed.

M/S: Veale/Oh

Members of the public were provided the opportunity to provide public comment. John Gray, representing Kaiser, indicated that Business and Professions Code section 4427.7 established the requirement to complete a self-assessment. Dr. Gray suggested changes to section 24.1 of form 17M-13 and section 29.3 of form 17M-39 related to ADDS self-assessment requirements.

Members considered the update comment, noting that changes to the motion were not necessary as the Chair can work with the Executive Officer to make changes necessary based on review of the legal requirements.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Oh	Support
Patel	Support
Sanchez	Not present
Serpa	Support
Veale	Support

Automated Drug Delivery Systems (17M-112)

Dr. Serpa advised members that new language was reflected on the form with a double underline and that the slide displayed provided a summary of the changes primarily included technical updates, changes to incorporate changes in regulation and statute.

Dr. Serpa recommended more clearly highlighting the requirement for licensure of an AUSD referenced in section 2.9 and agreed with changes offered.

Motion: Recommend approval of the proposed self-assessment form 17M-112. Authorize the Chair and Executive Officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency). Further, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing if requested. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed self-assessment form 17M-112 as noticed.

M/S: Veale/Oh

Members of the public were provided with an opportunity to provide public comment.

Public comment provided by John Gray requested changes similar to prior comments suggesting that self-assessment forms only need to be completed for ADDS that are licensed by the Board.

Members considered the comment and determined changes to the motion were not necessary because of the delegated authority to the Chair and Executive Officer to finalize the language consistent with the policy.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Oh	Support
Patel	Support
Sanchez	Not present
Serpa	Support
Veale	Support

VIII. Review and Discussion of Enforcement Statistics

Members were directed to the statistics provided in the meeting materials. Dr. Serpa noted the distribution of statistics was very interesting.

Members of the public were provided the opportunity to provide public comment; however, none were provided.

IX. Future Committee Meeting Dates

The Committee was reminded that future Committee meeting dates were included in the meeting materials.

X. Adjournment

Chairperson Serpa adjourned the meeting at 11:17 a.m.