



**ENFORCEMENT AND COMPOUNDING COMMITTEE
 MEETING MINUTES**

- DATE:** August 25, 2022
- LOCATION:** 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
 Renee Barker, Licensee Member
 Indira Cameron-Banks, Public Member
 Seung Oh, Licensee Member
- COMMITTEE MEMBERS NOT PRESENT:** Ricardo Sanchez, Public Member
- STAFF MEMBERS PRESENT:** Anne Sodergren, Executive Officer
 Eileen Smiley, DCA Staff Counsel
 Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at 9:04 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Jignesh Patel, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established. (Note: Licensee Member Barker was on the WebEx but was experiencing difficulties in establishing an audio connection.)

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.

The Committee heard comment from a retail pharmacist commenting about SB 362 requesting decisions are made on pending cases where this law was violated to assist retail pharmacists with the upcoming flu season. The pharmacist commented precedent needs to be established so that the chain pharmacies understand the law. The pharmacist commented on SB 1442 indicating chain pharmacies are circumventing the intent of the law to have someone available for the pharmacists by having untrained or inadequately trained people available. The pharmacist requested the wording be clarified to require someone in the pharmacy or have specific wording around training required for people who can help in the pharmacy.

The Committee heard a comment from a Savon/Albertsons who addressed the Board on three other occasions regarding companies who violate SB 442 and SB 362. The commentor noted the companies continue to ignore the requirements by providing an inaccurate list of names who can assist in the pharmacy. The pharmacists commented in about 6 of the 20 locations worked in, the company consistently doesn't have anyone to help the first or last few hours of the day where the pharmacist must work alone. The pharmacist noted many of the people on the list of people to help aren't HIPPA trained, haven't worked in a pharmacy and/or do not respond when called. The pharmacist stated the companies continue to do it because there is no enforcement.

The Committee heard a comment from a pharmacist with 40 years of experience who was a supporter of SB 1442 requesting the Board provide information and training to pharmacists about the rights of a pharmacist. The pharmacist noted it shouldn't be the burden of the pharmacist to speak up and make the company comply with the law. Currently, SB 1442 requires more work for the pharmacist in documentation and still the pharmacist stated she still works alone approximately 50 percent of the time. The pharmacist stated the staffing log should be a part of the Board inspection process. Companies should be investigated if there are violations. With the shortage of clerks and pharmacy technicians, awareness in the community should be fostered.

The Committee heard comment from a pharmacist agreeing with previous comments regarding the enforcement of SB 362 and setting a strong precedent

with the upcoming flu season. The commentor agreed with all comments regarding SB 1442 from previous commentors to underscore the urgency of the issues.

The Committee heard a comment from a floater pharmacist from Vons Inland Empire who reported working alone most during the last few hours of the day. The pharmacist is provided a list of people to call if help is needed but the people on the list are either not trained, not working or too busy to help. The pharmacist stated it was dangerous to work alone as a pharmacist. The pharmacist commented about receiving emails about quotas daily to encourage sales of “x” amount of shingles vaccines or specific medicines. The pharmacist stated the quotas are renamed as challenges or goals for the pharmacy but the pharmacist is asked to provide updates which creates great pressure for the pharmacist.

The Committee heard a comment from a Ralph's pharmacist-in-charge (PIC) who spoke about concern for quotas where complaints can only be filed against the companies if there are consequences for the quotas. The pharmacist stated concern for PICs being pressured into schedules where they don't have proper oversight over staff (e.g., change to 12-hour shifts, etc.).

The Committee heard a comment requesting the issue of PBM regulations being discussed as an underlying issue.

Chairperson Serpa acknowledged the comments regarding SB 1442 and SB 362 noting both items are on the radar of the Committee. Dr. Serpa added staff provide periodic updates on enforcement and education activities as well as encouraged reading the current issue of the Board's newsletter, The Script.

President Oh added the Board takes these issues very seriously and applauded those who spoke up.

Chairperson Serpa confirmed the attendance of Licensee Member Renee Barker.

III. Approval of July 19, 2022, Enforcement and Compounding Committee Meeting Minutes

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

Motion: Approve the July 19, 2022, Committee Meeting Minutes as

presented in the meeting materials

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided.

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

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

IV. Discussion and Consideration of Regulation of Surgical Clinics Pursuant to Business and Professions Code section 4190

Chairperson Serpa advised relevant sections of Pharmacy Law were detailed in the meeting materials including requirements covering the regulation of surgical clinics which are defined in Business and Professions Code section (BPC) 4190. As specified in this section, a surgical clinic licensed by the Board may purchase drugs at wholesale for administration from a co-mingled drug supply to patients registered for care at the clinic.

Chairperson Serpa continued the law specifies in BPC section 4192 that a surgical clinic is required to retain a consultant pharmacist to jointly approve policies and procedures used by the surgical clinic. A consulting pharmacist is required to visit the clinic regularly and at least quarterly to review operations and certify in writing if the clinic is operating in compliance with legal requirements. The written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

Chairperson Serpa recalled as part of the public comment received during the April 2022 Board Meeting, a commenter suggested that surgical clinics are not being inspected on a quarterly basis as required by consulting pharmacists. The commenter suggested that the Board perform education on the requirement and the issue was referred to the Committee for discussion. Dr. Serpa noted the commenter offered a solution; however, it appeared appropriate to also expand the consideration to the policy behind the legal requirement to determine if additional action may be appropriate.

Policy Question 1: Does the Committee wish to provide guidance to staff on the development of educational materials such as development of a newsletter article?

Chairperson Serpa stated support for education and newsletters article. Dr. Serpa noted it may also be appropriate to send out a reminder via the Board's subscriber alert system as surgical clinics are required to enroll in the Board's email notification system. Members Oh and Barker agreed education and raising awareness was a good place to start.

Policy Question 2: A consulting pharmacist is required to certify in writing if the clinic is operating in compliance. The clinic is required to maintain the reports; however, there is no mechanism to confirm that a consulting pharmacist has been retained and is completing the quarterly reports. What mechanism may be appropriate to confirm compliance with this provision? Also, should verification of compliance be incorporated into the annual renewal?

Chairperson Serpa stated support of including some requirement to confirm compliance with the provisions appeared appropriate. Dr. Serpa noted using the renewal process appeared as a possible way to do this as the licensee was already interacting with the Board on an annual basis through the renewal process.

Member Oh inquired if the Board inspected surgical clinics. Dr. Serpa advised the surgical clinics are inspected because of complaints and as part of routine inspections but few are inspected annually. Dr. Serpa noted the primary communication with the surgical clinics is through the renewal process. Dr. Oh stated all licensees need to be in compliance and spoke in support of the efforts to verify compliance through the annual renewals of the surgical clinic licensees.

3. The law is silent as to what action must be taken by a surgical clinic when an issue of noncompliance is identified. When a non-compliance issue is identified does the Committee believe development of a law or regulation to report noncompliance is appropriate?

Chairperson Serpa reviewed the presentation on the Board's inspection program from the July 2022 Committee meeting to determine if the Board was routinely inspecting clinics. Dr. Serpa stated while clinics are being inspected, it didn't appear the Board is able to inspect many clinics each year. Dr. Serpa presumed it is a resource issue as well as a reflection of the Board's direction to focus on performing inspections of pharmacies. Dr. Serpa noted the idea of requiring reporting noncompliance could be a way to ensure the Board can direct resources to surgical clinics that may be operating out of compliance and subject to an inspection by the Board.

Member Oh inquired if non-compliance is identified what steps could the Board take. Dr. Serpa advised at this time, non-compliance does not have to be reported by surgical clinics. Dr. Serpa noted the Board has the opportunity to create a law or regulation to make it a reportable event.

Member Oh inquired if confirmation through data can be received to verify that this is a widespread issue prior to adding a regulation. Dr. Serpa advised licensees aren't required to notify the Board of non-compliance and suggested using the renewal process to identify the scope of the issue as an option. Member Barker suggested including documentation that the surgical clinic met the requirement for the required consulting pharmacist on the annual documentation submitted at time of renewal.

Member Oh inquired how many clinics are licensed in California.

4. *The law does not currently detail out the specific elements of the consulting pharmacist's report. Does the Committee believe it is appropriate to develop a standardized reporting template, perhaps similar to a self-assessment form, that could be used by the consulting pharmacist?*

Chairperson Serpa commented the Board developed tools to assist some licensees with understanding provisions of law and has established a mechanism to perform self-evaluation. Dr. Serpa noted there is not currently such a tool for surgical clinics. Dr. Serpa added she believed the concept of a self-assessment tool is helpful because it assists licensees not only in evaluating for compliance, but also where non-compliance is identified, planning steps to achieve compliance. She noted this appeared consistent with the general policy behind the consultant pharmacist requirements including the provisions to verify compliance in writing and recommended corrective actions. Dr. Serpa added, if the Committee believed a standardize report was appropriate, she suggested the completion of the self-assessment should be required as a precursor to renewal as opposed to requiring a self-assessment on a quarterly basis.

Member Patel commented quarterly reporting, having a self-assessment process and a template would be ideal including reporting non-compliance. Dr. Serpa noted the periodic interval could be determined. Dr. Oh expressed concern that self-assessments are typically required every two years versus every year and spoke in support of consistency with the frequency of other self-assessments required by the Board. Dr. Serpa agreed consistency is important.

Member Barker confirmed surgical clinics renew on an annual basis so that the Board could require the surgical clinic to verify the requirement of the quarterly visit by a consulting pharmacist has been completed and the self-assessment could have more details.

Chairperson Serpa noted the Committee had consensus on requiring an acknowledgment of the consulting pharmacist with the quarterly reporting with the method and frequency to be further discussed.

5. Depending on the types of services provided at a surgical clinic, it is possible that sterile compounding may be performed. Should the self-assessment form include information about sterile compounding practices?

Chairperson Serpa recalled in previous meetings, the Committee briefly discussed sterile compounding practices that occur outside of board licensed pharmacies, hospital pharmacies, and outsourcing facilities. Dr. Serpa commented in favor of including documentation of sterile compounding practices as part of the self-assessment process.

Member Barker agreed data collection for types of sterile compounding practices (e.g., aseptic technique, training, safeguarding of sterile products, beyond use dates, etc.) happening in the surgical areas would be helpful to know the surgical clinics are following regulations. Dr. Barker noted including this in the self-assessment would be a good place to detail these practices. Member Oh agreed that data collection for sterile compounding prepared at clinics was a good idea.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa confirmed with Ms. Sodergren that sufficient information was provided for staff to develop a proposal for consideration by the Committee.

V. Discussion and Consideration of Barriers to Timely Case Resolutions

Chairperson Serpa advised this agenda item was deferred to a future agenda.

VI. Discussion and Consideration of Potential Draft Regulations Including a Self-Assessment Form Related to Outsourcing Facilities.

Chairperson Serpa stated in January and in response to changes in the law, the Board released FAQs providing guidance to outsourcing facilities that intend to dispense patient-specific prescriptions in California. At the end of the FAQs document a link to the Board's pharmacy self-assessment form was provided as another tool for outsourcers to use to aid in understanding the relevant provisions of pharmacy law related to dispensing of medications that are required when dispensing patient-specific medications.

Chairperson Serpa continued the FAQs provide a way to release necessary information quickly and efficiently to outsourcing facilities. Dr. Serpa noted as the Committee continues to implement this program, staff are recommending that the Committee consider building on the FAQs and provide more regulatory guidance to outsourcing facilities through the development of regulation language. Based on BPC section 4129, the Legislature contemplated development of regulations and explicitly authorized adoption of regulations in the section.

Chairperson Serpa referenced the meeting materials where staff was suggesting development of regulations as well as an outsourcing specific self-assessment form to aid licensees with compliance. Dr. Serpa recalled the Board uses self-assessment forms for several of its license types to facilitate compliance through self-evaluation.

Chairperson Serpa referenced the meeting materials that included concept regulation language and a conceptual self-assessment form. If the Committee agreed, staff could work to develop a more robust proposal for future consideration. Dr. Serpa noted willingness to work with staff to provide direction as needed and consistent with past practices of this Committee.

Chairperson Serpa expressed comfort with the policy proposal and thought it warranted additional development by staff for the Committee to consider at a future meeting. Dr. Serpa noted support in providing education to licensees and believed self-assessment forms play a significant role in education, if licensees take the opportunity to perform a meaningful assessment of operations.

Members were provided the opportunity to comment.

Member Oh inquired if the effort was worth it for a small subset of licensees consisting of 21 facilities. Dr. Serpa noted the subset was small but the subset was high risk and prone to problems. Dr. Serpa thought the FAQs would be sufficient but is now finding it is not sufficient. The regulation would be required to develop the self-assessment. Ms. Sodergren added as implementation has continued, it appeared appropriate to provide additional guidance to licensee. The Board was

recommended to promulgate regulations. Dr. Serpa noted public comment about how the outsourcers were confused about patient-specific prescriptions that prompted the FAQs but the FAQs didn't solve the issue. Dr. Oh requested confirming with outsourcers that there is interest in doing patient-specific prescriptions. Dr. Serpa noted it does come up in the compounding discussions. Ms. Sodergren provided when AB 1533 passed, the Board received public comment asking for guidance on how to outsourcers were to perform the patient-specific prescriptions. Members were in support of moving forward.

Members of the public were provided the opportunity to comment. The Committee heard comment from a pharmacist that the self-assessment for outsourcing facilities was a good idea and liked reinforcing the good faith examination.

The Committee was agreeable to the Chairperson working with staff to refine the proposal and underlying policy to discuss at a future meeting.

VI. Discussion and Consideration of Proposed Change to the Board's Citation and Fine Authority Related to Unlicensed Activity

Chairperson Serpa referenced meeting materials detailing out some of the general provisions for the Board's citation and fine program noting for purposes of the discussion, the Committee would focus specifically on citations issued for unlicensed activity. Dr. Serpa advised the policy question is the Board's current fine authority related to unlicensed activity and to determine if the Committee should offer a recommendation for a change. Dr. Serpa noted meeting materials indicated the Board issued 72 citations for unlicensed activity last year.

Chairperson Serpa advised although citations and fines are not posted on the Board's website, they are public information. Dr. Serpa continued as the Board's Vice-President for several years, she and the President have had the opportunity to review closed citations. Dr. Serpa noted at times an entity may have provided pharmacy services in an unlicensed capacity, including dispensing prescriptions into California without a license. When an investigation reveals such unlicensed activity generally the maximum fine the Board can issue to the entity is \$5,000. Dr. Serpa stated she was not confident that was a sufficient response in some instances.

Chairperson Serpa added BPC section 4126.5(c) provides authority for the Board to issue a citation for violations of the section for each occurrence, as opposed to for each investigation. Dr. Serpa noted this section of the law generally describes who a pharmacy may furnish dangerous drugs to and provides that non-compliance with the provision provides for assessment of a fine for each occurrence rather than for each investigation. Dr. Serpa added from a policy standpoint, such an approach for unlicensed entities may provide some parity with potential outcomes

for pharmacies generally furnishing to unauthorized entities. Dr. Serpa continued she believe that not all citations warrant a fine exceeding \$5,000, but where the egregiousness of the violations is appropriate, the Board should have the option, especially given the Board cannot impose discipline.

Members were provided the opportunity to comment.

Member Oh stated \$5,000 was not enough to address unlicensed activity and inquired if legislation or another avenue was required to facilitate a change. Ms. Sodergren provided BPC 4126.5 (c) was provided to demonstrate pharmacy law had a process where it recognizes that a fine in certain circumstances may be based on the assessment per occurrence versus a per investigation model that is typically used. Ms. Sodergren noted this is precedent in pharmacy law but believed it would require statutory change. Ms. Sodergren noted citation and fine authority can and does change as needed.

Member Patel inquired if a non-licensed entity had 15 violations would the entity be charged \$75,000. Ms. Sodergren stated it would depend on the Board's policy. If the Committee believed the per occurrence model was appropriate, it would be but noted there are ranges in cite and fine authority.

Member Oh spoke in strong support of policy for fines with each occurrence of unlicensed activity. Dr. Oh noted deep concern for out of state unlicensed entities shipping into California.

Member Barker commented concern for who the unlicensed entities are and inquired the licensure cost. Ms. Sodergren provided the application fee is \$570. Dr. Barker noted cost was not a barrier to do business in California. Dr. Barker expressed concern with the FDA finding the adulterated nonprescription products made by various entities and the quality of the products.

Member Oh voiced concern for the proliferation of nonlegitimate online businesses. Dr. Oh stated California should take a strong stand against the nonlegitimate businesses shipping into California.

Members of the public were provided the opportunity to comment.

The Committee heard a comment from a representative of UFCW Western States Council who echoed comments of Board Members stated to ensure and deter bad behavior by non-licensed entities, the penalties need to be something that deters the behavior. Low or minimal penalties does not deter non-licensed entities from operating without a license.

The Committee was agreeable to the Chairperson working with staff to refine the proposal and underlying policy to discuss at a future meeting.

VII. Future Committee Meeting Dates

Chairperson Serpa advised the October 19, 2022, Committee meeting was canceled. Dr. Serpa noted in anticipation of USP releasing its finalized revised compounding chapters, the Committee had established additional dates to allow time for the review and consideration of the revised chapters and an opportunity to determine if changes to the Board's compounding regulations was appropriate. As final publication had not occurred, the October 19 meeting was not necessary. The Committee will continue to monitor for updates from the USP and will keep members apprised of potential impacts to the meeting schedule.

XII. Adjournment

The meeting adjourned at 10:22 a.m.