California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE: October 20, 2021

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
Ricardo Sanchez, Public Member

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

The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included; Jignesh Patel, Seung Oh, Ricardo Sanchez, 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.

Public comment included a request for the Committee to discuss an enforcement issue related to e-prescribing and the upcoming California requirements related to forwarding an electronic controlled substances prescription to another pharmacy. Comments noted challenges created because of the lack of National Council for Prescription Drug Programs (NCPDP) standards in this area. As part of the

comments members were advised that standards are under development but will not be completed until 2024 and requested a delay in enforcement until NCPDP standards.

Public comment also suggest that the Board perform education on the requirement for e-prescribing for pharmacists that prescribe medications.

Debbie Veale joined the meeting at 9:10.

Members agreed to agendize this issue as part of the December 2021 Board Meeting.

III. Approval of July 15, 2021, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes. Members identified changes to the minutes to correct references made to Member Oh as Vice Chair; correct references made to Member Veale as "Dr."; amend page 5, last paragraph on section 5 to, "*In response, Dr Serpa stated that the current checklist provides information for all licensed categories, however, some items may not apply to all.*"; amend page 13, item 9, last sentence, "*Dr. Serpa requested language clarification be added for hospitals that are using ADDS for discharge prescriptions after hours.*"

Motion: Approve the July 15, 2021 Committee Meeting minutes with changes noted.

M/S: Sanchez/Patel

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

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Oh	Support
Patel	Support

Sanchez	Support
Serpa	Support
Veale	Support

IV. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

Dr. Serpa referenced the meeting materials. Several measures were recently signed that impact the practice of pharmacy. For each bill a summary was provided as well as information on implementation.

Assembly Bill 107

Dr. Serpa informed members that Assembly Bill 107 is related to veterans and military spouses. This measure will require the Board to issue a temporary license to practice within 30 days of the Board receiving the results of a fingerprint background check. The measure does require an applicant for a pharmacist license to take and pass the CPJE as a precursor to issuance of the temporary license.

Dr. Serpa advised members that the provisions take effect July 1, 2023, which will provide the Board time to complete necessary implementation activities including changes to application and instruction updates, changes and changes to data systems and develop of regulations.

As part of its discussion the Committee indicated referral to the Licensing Committee for development of the regulations would be appropriate.

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

Assembly Bill 527

Chairperson Serpa noted that Assembly Bill 527 includes the Board's sponsored provision to exempt specified non-narcotic combination product controlled substances from the California controlled substances. Members noted that implementation efforts should be minimal and include education on the change.

Members of the Committee and public were provided with the opportunity to provide comments; however, none were provided.

Assembly Bill 1064

Dr. Serpa highlighted that Assembly Bill 1064 expands authority to allow a pharmacist to independently initiate and administer any vaccine that has been approved or authorized by the FDA and received a recommendation by the Advisory Committee on Immunization Practices. Chairperson Serpa noted that implementation efforts will focus primarily on education of the change.

Members of the Committee and public were provided with the opportunity to provide comments.

Public comment was received from the California Pharmacists Association, the sponsor of the bill, expressing appreciation of the Board's support and noted the expanded role for pharmacists.

Assembly Bill 1533

Chairperson Serpa advised members that Assembly Bill 1533 (our Sunset bill), contains a number of changes in Pharmacy Law.

Dr. Serpa noted that the measure extends the operations of the Board until January 1, 2026. The Committee agreed that the Board should receive an annual report of many of the reporting elements of the Sunset Report which could be reviewed as part of the July meeting.

Members did not have comments on this provision.

Dr. Serpa informed members that Section 4052(a)(13) amends 4052 to expand authority to pharmacists to initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement and also expands authority for pharmacists to provide medication assisted treatment pursuant to a state protocol.

Implementation efforts will include the Board's development of a state protocol to facilitate implementation of the MAT authority.

Members noted that it was appropriate for the Licensing Committee to develop the regulations for MAT. Members also noted that the expansion of collaborative practice was appropriate.

Dr. Serpa advised members that Business and Professions Code Section 4052.6 was amended to expand the authority for an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy beyond health care facilities. The Committee discussion included that implementation efforts will focus primarily on education about the provision and should reiterate the provisions for coordination for care and education with the diagnosing prescriber.

Dr. Serpa highlighted the changes in Business and Professions Code Sections 4110 and 4126.10 are changes sought to implement provisions of the FDA MOU addressing certain distributions of compounded drugs. Specifically, pharmacy license renewal requirements will include notification of compounding practices for pharmacies distributing compounding human preparations as well as reporting requirements established in the MOU. Implementation efforts will include updating renewal forms and data systems as well as the development of educational materials.

Members did not have comments to the changes to the sections.

Dr. Serpa advised that Pharmacy Law was also amended to allow outsourcing facilities licensed by the Board to dispense patient-specific compounded drug preparations under specified conditions, including that such dispensing shall comply with the same requirements of a pharmacy.

Chairperson Serpa indicated that implementation efforts will include development of educational materials and it is anticipated that extensive education to outsourcing facilities will be required noting that such education is necessary to allow harmony with federal allowances while ensuring patients have access to pharmacist care, including drug utilization review, patient-centered labeling, and patient consultation requirements.

Members did not have comments to the changes to the sections.

Dr. Serpa summarized the change to Section 4161 which was amended to create alternative pathways to licensure for nonresident third-party logistics providers. Implementation efforts will include updating application instructions and forms. Dr. Serpa referenced the meeting materials which included that staff will need to begin working with facilities granted temporary licenses to those entities currently under the Board's waiver process for purposes of distributing ventilators and vaccines into California. This work will need to be completed prior to the expiration of the temporary licenses to ensure continuity to the effective date of this new law, January 1, 2022.

Members did not have comments to the changes to the Section 4161.

Chairperson Serpa highlighted that changes to Section 4210 alter application requirements for an advance practice pharmacist recognition to allow for qualification under a single pathway, if that pathway includes completion of a second criterion. Dr. Serpa noted that the change clarifies the requirements and eliminates the current confusing language. Dr. Serpa summarized implementation efforts which include updating application instructions and forms as well as development of educational materials. In addition, staff will review pending applications to determine if the changes in the requirements will impact applicant eligibility.

Members did not have comments to the changes to the Section 4210.

Dr, Serpa notified members that Business and Professions Code Section 4232.5 was amended to require a pharmacist with authority to prescribe a controlled substance to complete an educational course on the risks of addiction to Schedule II drugs. Implementation efforts will include updating the renewal application requirements via regulation. The regulation will give notice of the requirement and how an individual will demonstrate compliance.

The Committee determined that the Licensing Committee would be well suited to develop the regulations and should include other CE topics that are required as well.

Dr. Serpa noted under the provisions of this bill, the Board will be required to convene a working group of interested stakeholders to discuss whether moving to a standard of care model is feasible and appropriate. Chairperson Serpa continued that as included in the measure, the Board will be required to submit a report with recommendations to the Legislature by July 1, 2023 following completion of the workgroup.

President Oh advised members that education will be provided in January and members will be provided the opportunity to elect to participate in the ad hoc committee to consider the matter.

Dr. Serpa noted that under the provisions established in Section 4317.5 the Board will have new fine authority to address repeated violations under specified conditions including that the violations occurred in community chain pharmacies operating under common ownership. Chairperson Serpa highlighted that the measure provides for an opportunity for the pharmacy to cure a violation, as long as the violation did not result in actual harm to any consumer or pose serious potential harm to the public.

It was noted that implementation will include education about the provisions and the Committee will be provided with data on implementation of this new fine included as part of the annual presentation the Committee receives on the Board's citation and fine program.

Members did not have comments on BPC 4317.5

Dr. Serpa reviewed Section 4427.65 which expands the locations where unit-dose automated drug delivery systems may be located, noting that implementation will include education on the provisions.

Members did not have comments on BPC 4427.65

Members of the public were provided with the opportunity to provide public comment on AB 1533.

Public comment included comments related to changes in Section 4126.10. Comments noted that information required to be reported indicated the MOU may be pushed back beyond October 2022, suggesting that the Committee should consider delaying enforcement or enforcement discretion on the reporting comments.

Senate Bill 306

Dr. Serpa highlighted that under the provisions a pharmacist will be allowed to dispense a medication without an individual name if the prescription includes "expedited partner therapy" or EPT. Chairperson noted that the bill requires a pharmacist to provide a written notice that describes the right of an individual receiving EPT to consult with a pharmacist about the therapy and potential drug interactions. Implementation efforts will focus primarily on education of the measure.

Members did not have comments on the provisions of Senate Bill 306.

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

Senate Bill 310

Chairperson Serpa informed members that Senate Bill 310 creates a medication collection and distribution program that allows for patients to donate previously dispensed medication back to a participating practitioner or physician for redistribution to other patients of the same practitioner. Dr. Serpa noted that under the provisions of the measure the Board has the authority to request records to evaluate for compliance with the provisions and has the authority to prohibit a practitioner from participating in this program under specified conditions. Implementation will focus on education about the provisions as well an extensive education of identified Board staff to assure practitioners have appropriate policies and procedures, documentation of drug manufacturing requirements and to ensure appropriate patient protections exist. Data on this new program will be collected and reported to our Committee.

Members did not have comments on the provisions of Senate Bill 310.

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

Senate Bill 311

Dr. Serpa noted that Senate Bill 311 requires health care facilities to allow a terminally ill patient to use medical cannabis under specified conditions. Late amendments to the measure specified that health care facilities permitting such use must comply with

drug and medication requirements applicable to Schedule II – IV drugs and shall be subject to enforcement actions by the California Department of Public Health.

Dr. Serpa advised members that late amendments to the bill created conflicts within the measure itself. Specifically, the amendments to require the medicinal cannabis to comply with provisions related to Schedule II-IV medication creates a number of questions about the applicability of Board regulations including storage, inventory control, acquisition and the role of Pharmacy in these facilities.

The Committee considered if it was appropriate to determine what the Board's role should be in resolving these conflicts along with other regulators and stakeholders noting there are other challenges with this measure that may be outside of the Board's purview, but problematic for health systems. Concerns included federal implications to allowing the use of medicinal cannabis in health care facilities that could negatively impact their licensure, accreditations or reimbursement.

Members sought clarification on the measure and the applicability and were advised the medicinal cannabis was not rescheduled under the provisions of the bill.

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

Linda Panofsky, UCSF, was read into the record because of technology challenges. Ms. Panofsky suggested the Board, in conjunction with CDPH, consider strengthening patient medication regulations.

Dr. Stein advised the Committee that late amendments included in Section 1649.3 seemed to be contradictory to other provisions of the bill and indicated that it may not have much applicability. Dr. Stein also noted it is interesting that the California Department of Public Health is charged with enforcement of the provision.

Lori Hensic, Scripps Health, shared with members that conversations with the author's office confirm medicinal cannabis was not rescheduled and noted conflicts were previously discussed. The author clarified that it was not their intent to hold the pharmacy responsible and requested a letter be published in the journal. [**Note**: A letter published in the assembly or daily journal is a tool authors use to clarify ambiguity in a bill or clarify intent.] Dr. Hensic continued that the measure raises several questions, including questions of acquisition, disposition, and inventory control and offered to assist the Committee in its further discussion.

Keith Yoshizuka noted agreement with the Board's assessment and the need to further refine the requirements. Dr. Yoshizuka highlighted the potential consequences of the bill including that hospitals could lose their federal funding.

Steven Gray commented that the medical cannabis law in California is very old. He noted that certain hospitals appear to allow the use of medical cannabis. Dr. Gray noted that Federal law prohibits DEA from taking action against a hospital that allows the use of medical cannabis.

Following public comments, members requested that staff come back to the Committee with recommendations on education of the measure.

Senate Bill 362

Dr. Serpa advised members that Senate Bill 362 will prohibit a community chain pharmacy from using a quota to evaluate the performance of a pharmacist or pharmacy technician. Dr. Serpa noted that implementation efforts will include education about the provisions as well as the process a pharmacist or pharmacy technician may use to file a complaint and education about whistleblower protections. Members were advised that the Committee will receive data on implementation of this new law.

Members did not have any additional comments on Senate Bill 362.

Members of the public were provided the opportunity to provide public comment. Public comment was received from a representative from UFCW indicating that UCFW looks forward to working with the Board to implement the provisions and thanked the Board for its support of the measure.

Chairperson Serpa advised members that Senate Bill 409 expands authority for pharmacists to provide CLIA-waived tests under specified conditions. Implementation will include education on the provisions and that the Board's Health Services Registry should be updated to include these additional patient care services.

Members did not have any additional comments on Senate Bill 409.

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

The meeting was in recess from 10:13 to 10:23. Roll call was taken upon resumption of the meeting. Members present: Jignesh Patel, Seung Oh, Ricardo Sanchez, Debbie Veale and Maria Serpa.

V. Discussion and Consideration of Released Revised Proposed Changes to USP Chapters 795 and 797 and the Board's Current Policy Statement

Dr. Serpa indicated relevant law sections are detailed in the meeting materials, and highlighted that under Section 4127, the Board is required to review any formal revisions to USP Chapter 797 no later than 90 days after the revisions become official to determine whether amendments are necessary for Board regulations. Chairperson Serpa noted that in 2019 during many stakeholder meetings to update current pharmacy regulations, review and consideration of the USP Chapters requires a significant amount of member time. This work was put on hold when USP paused their implementation date to look at additional changes to their proposed language.

Given that, with the release of the newly revised proposed chapters, Dr. Serpa suggested it is appropriate to resume work on updating compounding regulations. Dr. Serpa referenced the meeting materials included high level comparison charts to USP 795 and 797 noting that the information will assist the Committee in future efforts.

Dr. Serpa suggested the first step for the Committee is to review the Board's current policy statement and update it, followed by monitoring the USP process in finalizing the standards and restart stakeholder meetings on compounding in 2022.

Members were provided the opportunity to comment on the plan moving forward.

Dr. Serpa transitioned to discussion on the need and text of the draft policy statement noting it is important to provide stakeholders with an update on the status of compounding to ensure the Board's regulated public has a clear understanding of the applicable laws and standards that must be followed to compound drug preparations.

Members considered the updated draft policy statement.

Motion: Recommend to the Board approval of the draft policy statement.

M/S: Oh/Veale

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

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Oh	Support

Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support

VI. Updates on FDA Actions Related to Human Compounding

Dr. Serpa noted that the meeting materials included two items for information only. The information was provided not only for the Committee's information, but to inform stakeholders.

Dr. Serpa advised members of the notice of extension released by the FDA relating to the MOU on Interstate Distribution of Compounded Drug Products. As included in the notice, the FDA is extending the period for a state to enter the MOU until October 27, 2022. Dr. Serpa noted that the extension will allow the Board time to implement necessary provisions.

Dr. Serpa informed members of the October 7, 2021 release by the FDA of a draft guidance document titled, Hospital and Health System Compounding Under Section 503 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. The guidance describes how the FDA intends to apply certain provisions of Section 503 A to human drug products that are compounded by state-licensed pharmacies for distribution within a hospital or health-system. Dr. Serpa advised members that written comments must be submitted by December 6.

Members did not have additional comments.

Members of the public were provided with the opportunity to provide public comments. Public comment questioned what other steps are necessary for the Board to sign the MOU. Counsel advised that the Committee has previously discussed this issue and the commenter was referred back to those previous discussions.

VII. Review and Discussion of Enforcement Statistics

Dr. Serpa referenced the enforcement statistics provided in the meeting materials.

Members were provided the opportunity to provide comments; however, none were provided.

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

comment; however, none were provided.

VIII. Future Committee Meeting Dates

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

IX. Adjournment

Chairperson Serpa adjourned the meeting at 10:35 a.m.