California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: October 4, 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
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT:
Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Gina Tomaselli, 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 9:02 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; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensing Member. 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.

The Committee heard a comment regarding a request for the Board to clarify its

position with respect to using the 503A and 503B bulk list given by the FDA for compounding a bulk drug substance unapproved by the FDA.

Chairperson Serpa provided background indicating this has been discussed in the past and will be discussed as part of the USP discussions in the future. Members agreed to discuss this as part of the USP discussion.

III. Approval of August 25, 2022, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes; however, no comments were made.

Members Barker and Cameron-Banks joined the meeting at approximately 9:10 a.m.

Motion: Approve the August 25, 2022, Committee Meeting Minutes as presented in the meeting materials

M/S: Patel/Sanchez

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

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Barker	Yes
Cameron-Banks	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes

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

Chairperson Serpa advised the Committee would continue the discussion on the regulation of surgical clinics. Dr. Serpa referenced meeting materials that included relevant sections of Pharmacy Law covering the regulation of surgical clinics which are defined in Business and Professions Code (BPC) section 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. Dr. Serpa further explained 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. Additionally, a consulting pharmacist must 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. Written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

Chairperson Serpa provided background on the Committee's prior discussion including direction provided to staff after considering policy questions were included in the meeting materials. Dr. Serpa added following the last Committee meeting, inspector staff performed some inspections of surgical clinics to provide further information to the Committee as part of the policy consideration. Dr. Serpa thanked Board inspector staff. Dr. Serpa noted meeting materials include inspection findings including the most frequent discussion items and orders of corrections issued. Dr. Serpa added the findings appear to support the need to further refine the Board's regulation of surgical clinics and the development of a self-assessment process to facilitate compliance.

Chairperson Serpa referred to draft statutory language developed for consideration today. Dr. Serpa noted as proposed to be amended, renewal requirements would be amended to include confirmation of compliance with quarterly inspections by the consultant pharmacist and as part of the renewal every odd numbered year, the renewal would also require submission of the most recent self-assessment. Dr. Serpa continued as proposed, the statute would also be amended to establish the self-assessment requirement. Dr. Serpa noted consistent with the Committee's discussion in August, the self-assessment frequency would be consistent with other license types.

Members were provided an opportunity to provide comments. Member Oh inquired if this was specific to surgical clinics. Ms. Sodergren confirmed the proposed statutory language was specific to surgical clinics.

Motion: Recommend to the Board to pursue statutory change to BPC

4204 and 4192 as it relates to surgical clinics as reflected in the meeting materials.

Proposed Amendment to Business and Professions Code section 4204 as follows:

(a) Each application for a license under Section 4190 shall be made on a form furnished by the board. The form of application for a license under this article shall contain the name and address of the applicant, whether the applicant is licensed, the type of services the facility will offer, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.

(b) Each initial application shall contain a statement from a consulting pharmacist certifying that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of health and safety of the public. Upon the filing of the application and the payment of a fee in subdivision (s) of Section 4400, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for a license. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license. The board shall not however, investigate any matters connected with the operation of a premises, including operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made do not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under Section 4190, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4190. The license shall be renewed annually upon payment of a renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable. <u>As part of the renewal process the consulting pharmacist shall certify compliance with the quarterly inspections as required in</u>

Section 4192. Further, as part of the renewal process of every odd numbered year, the most recent self-assessment form completed as provided in Section 4192 shall also be provided to the Board.

Proposed Amendment to Business and Professions Code section 4192 as follows:

(a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete a Surgical Clinic Self-Assessment Form as determined by the board as a means to promote compliance through self-examination and education. The self-assessment shall assess the clinic's compliance with current laws and regulations and include information on compounding practices as specified on the most recent version of the Surgical Clinic Self-Assessment Form approved by the Board and posted on its website. The professional director of the clinic and consulting pharmacist shall certify on the final page of the Surgical Clinic Self-Assessment Form that they have read, reviewed and completed self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the Board. The completed form shall be signed under penalty of perjury and kept on file in the clinic for three years and made available to the Board or its designee upon request.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

M/S: Oh/Patel

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

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Barker	Yes
Cameron-Banks	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes

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

Chairperson Serpa provided as discussed during the August meeting and in response to changes in the law, in January of this year the Board released FAQs providing guidance to outsourcing facilities that intend to dispense patient-specific prescriptions in California. Dr. Serpa noted at the end of the FAQs a link to the Board's pharmacy self-assessment form was provided as another tool for outsourcers to use to aid them in understanding the relevant provisions of pharmacy law related to dispensing of medications that are required when dispensing patient-specific medications. Dr. Serpa recalled at the last meeting, staff provided concept regulation language and a conceptual self-assessment form. Dr. Serpa advised since the last meeting, staff and counsel have refined the proposal

included in the meeting materials. Dr. Serpa noted comfortableness with the updated regulation text and draft self-assessment form.

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

Motion: Recommend initiation of a rulemaking to add Title 16, California Code of Regulations sections 1750 and 1750.1 Related to Outsourcing Facilities. Delegate to the Executive Officer authority to make any technical or non-substantive changes that are identified through the pre-review process and release for the public comment period. 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, make any nonsubstantive changes to the package and adopt the regulation.

Proposal To Add Article 6.5 and Sections 1750 and 1750.1 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 6.5 Outsourcing Facilities

1750 Outsourcing Facility Requirements

(a) Each outsourcing facility defined under section 4034 of the Business and Professions Code shall compound all sterile products and nonsterile products in compliance with federal current good manufacturing practices (cGMP) applicable to outsourcing facilities under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)) and shall meet the requirements of this Article.

(b) In addition to subsections (a) and (c), an outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall comply with all applicable federal and state laws and regulations, including all of the following:

(1) Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 (commencing with section 1700.1) – Poison Prevention Packaging,

(2) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 (commencing with section 210.1) – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General,

(3) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 (commencing with section 211.1) – Current Good Manufacturing Practice for Finished Pharmaceuticals,

(4) Code of Federal Regulations, Title 21, Chapter II, Parts 1301 (commencing with section 1301.01) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances,

(5) Code of Federal Regulations, Title 21, Chapter II, Part 1304 (commencing with section 1304.01) – Records and Reports of Registrants with the Drug Enforcement Administration,

(6) Code of Federal Regulations, Title 21, Chapter II, Part 1305 (commencing with section 1305.01) -- Orders for Schedule I and II Controlled Substances,

(7) Code of Federal Regulations, Title 21, Chapter II, Part 1306 (commencing with section 1306.01) -- Prescriptions,

(8) Code of Federal Regulations, Title 21, Chapter II, Part 1311 (commencing with section 1311.01 -- Requirements for Electronic Orders and Prescriptions,

(9) The Uniform Controlled Substances Act (Health and Safety Code, Division 10 (commencing with section 11000),

(10) Chapters 1, 4, 6 and 8 of the Sherman Food, Drug, and Cosmetics Law (Health and Safety Code, Division 104, Part 5 (commencing with Section 109875) -,

(11) United States Code, Title 21, Chapter 9, Subchapter V, Part A (commencing with section 351) – Drugs and Devices, and,

(12) United States Code, Title 21, Chapter 13, Part C (commencing with section 821) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, except for sections 821, 822a, and 826a of that Part.

(c) An outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall dispense patient-specific compounded preparations pursuant to a prescription for an individual patient in compliance with all applicable provisions of state and federal laws and regulations relating to a pharmacy as follows:

(1) Orally transmitted prescriptions are received and reduced to writing by a pharmacist consistent with the provisions of Business and Professions Code section 4070 and section 1717(c) of this Division and are issued by an appropriately licensed prescriber.

(2) Internet prescriptions are only dispensed pursuant to a prior good faith examination as required in Business and Professions Code section 4067(a) and are issued only by an appropriately licensed prescriber.

(3) Electronic prescriptions meeting the requirements of Business and Professions Code section 688 are issued only by an appropriately licensed prescriber.

(4) Controlled substances prescriptions meet the requirements of Health and Safety Code sections 11164(a), 11164.5, 11167.5, and 11162.1 and Business and Professions Code section 688.

(5) Each prescription contains all information required by Business and Professions Code sections 4040 and 4070.

(6) Each prescription label complies with the provisions of Business and Professions Code sections 4076, 4076.5, and 4076.6 and section 1707.5 of this Division.

(7) Drug warnings are provided orally or in writing consistent with the provisions of Business and Professions

Code sections 4074 and 4076.7, section 1744 of this Division, and section 290.5 of Title 21 of the Code of Federal Regulations.

(8) Prescriptions are dispensed in containers meeting the requirements of section 1473(b) of Title 15 of the United States Code, section 1700.15 of Title 16 of the Code of Federal Regulations, and section 1717(a) of this Division.

(9) Patient consultation is provided consistent with the provisions of section 1707.2 of this Division.

(10) Prior to consultation as required in section 1707.2, a pharmacist shall review drug therapy and patient medication records consistent with the provisions of section 1707.3 of this Division.

(11) The facility shall maintain medication profiles consistent with the provisions of section 1707.1 of this Division.

(12) All Schedule II through V controlled substance dispensing data are reported to the CURES Prescription Drug Monitoring Program as required in Health and Safety Code section 11165.

(13) A pharmacist communicates with the patient or patient's agent if a medication error occurs consistent with the provisions of section 1711.

(14) Medication errors must be documented as part of the facility's quality assurance program consistent with the provisions of Business and Professions Code section 4125 and section 1711 of this Division.

(15) Patient information and prescriptions are kept confidential consistent with the provisions of the Confidentiality of Medical Information Act (Civil Code sections 56 and following), and section 1764 of this Division.

(16) Prescription refills must comply with Business and Professions Code section 4063, Health and Safety Code section 11200, and sections 1717 and 1717.5 of this Division.

(17) All records of disposition are maintained for at least three years consistent with Business and Professions Code sections 4081 and 4105.

(d) For the purposes of this section, "appropriately licensed prescriber" shall mean any health care professional listed in Section 4040(a)(2) of the Business and Professions Code.

Proposal to Add Section 1750.1 to Article 6.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1750.1 Self-Assessment of an Outsourcing Facility (Resident and Nonresident)

(a) Each outsourcing facility as defined under section 4034 of the Business and Professions Code shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the outsourcing facility's designated quality control personnel, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, for compliance with federal current good manufacturing practices as referenced in section 1750 (cGMP) and provisions of state law related to pharmacies, Pharmacy law and this Division related to patient specific prescriptions. For the purposes of this section, "designated quality control personnel" shall mean an individual or individuals from the quality control unit as defined in section 211.22 of Title 21 of the Code of Federal Regulations ("quality control unit") identified by the outsourcing facility as the person or persons responsible for the facility's operations as detailed in the FDA Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, Guidance for Industry.

(b) Each outsourcing facility shall designate a member of the quality control unit to be responsible for compliance with this section. The name and job title of the designated member must be maintained as part of the records of the outsourcing facility in accordance with Business and Professions Code section 4081.

(c) In addition to the self-assessment required in subdivision (a) of this section, the designated quality control personnel shall complete a self-assessment within 30 days whenever:

(1) A new outsourcing facility license is issued.
(2) There is a change in the designated quality control personnel.
(3) There is a change in the licensed physical location of an outsourcing facility to a new address.

(d) Each outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall complete the "Outsourcing Facility Self-Assessment," Form 17M-117 (New. 9/2022), which is hereby incorporated by reference and contains the following components:

(1) The designated quality control personnel shall provide identifying information about the outsourcing facility including:
(A) Name, license number of the premises, and the license expiration date;
(B) Address, phone number, website address, if applicable, and type of ownership;
(C) U.S. Food and Drug Administration (FDA) Federal Establishment Identification number, expiration date and date of most recent inspection completed by the FDA pursuant to Section 360 of Title 21 of the United States Code;
(D) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory pursuant to Title 21, Code of Federal Regulations section 1304.11; and,
(E) Hours of operation of the licensee.

(2) The designated quality control personnel shall list the name of each staff person involved in the dispensing of patient specific prescriptions at the facility at the time the self-assessment is completed, and each person's role within the facility's operations.

(3) The designated quality control personnel shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated quality control personnel shall provide a written corrective action or action plan describing the actions to be taken to come into compliance with the applicable law or regulation cited on the self-assessment form for which a "no" response was provided.

(5) The designated quality control personnel shall initial each page of the self-assessment form with original handwritten initials in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(6) The designated quality control personnel shall certify, under penalty of perjury of the laws of the State of California, on the final page of the self-assessment that:

(A) They have completed the self-assessment of the licensed premises for which they are responsible;

(B) Any deficiency identified within the self-assessment will be corrected and list the timeframe for correction;

(C) They acknowledge receiving the following notice: "All responses on this form are subject to verification by the Board of Pharmacy"; and,

(D) The information provided in the self-assessment form is true and correct.

(E) The certification, made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct, may be an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and have received notice that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. The certification shall be

made, under penalty of perjury of the laws of the State of California, that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(e) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection in accordance with Business and Professions Code section 4081.

(f) The outsourcing facility is responsible for compliance with this article.

(g) Any identified areas of deficiency identified in the self-assessment shall be corrected as specified in the timeframe listed in the certification as provided in subsection (d)(6).

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4034, 4129- 4129.9, Business and Professions Code.

[Note: A copy of the draft self-assessment is attached to the meeting materials.]

M/S: Oh/Sanchez

Members of the public were provided with an opportunity to provide public comment. A member of the public requested clarification how differs from FDA requirements or is it redundant.

Chairperson Serpa advised the Board provided guidance through FAQs for outsourcers providing patient specific prescriptions. Dr. Serpa advised after the FAQs were provided, it was determined additional guidance was needed. Counsel Smiley further clarified outsourcers are now able to provide patient specific prescriptions to California residents. Dr. Serpa noted the proposed regulation and self-assessment addresses this issue of patient specific prescriptions provided to California residents.

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Barker	Yes
Cameron-Banks	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes

Chairperson Serpa thanked the Board and staff for their diligent work on these two issues.

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

Chairperson Serpa referenced meeting materials including some of the general provisions for the Board's citation and fine program. Dr. Serpa noted at the last meeting, the Committee discussed the patient risks associated with unlicensed activity including the potential distribution of adulterated products and also determined that the Board's current maximum fine amount is not sufficient to address unlicensed activity.

Chairperson Serpa noted after the August meeting, staff developed a possible statutory proposal for consideration included in the meeting materials. Dr. Serpa stated the language establishes the same approach as the fine provisions established in BPC 4126.5(c).

Chairperson Serpa stated she was comfortable with the draft proposal and emphasized not all unlicensed activity citations warrant a fine exceeding $5,000, but where the egregiousness and the violations are significant, Dr. Serpa believed the Board should have the option to impose discipline.

Motion: Recommend to the Board to pursue a statutory proposal consistent with the policy discussion to increase fine assessment for unlicensed activity.

Statutory Proposal to Add Business and Professions Code Section

4316.5
Notwithstanding any other law, the Board may assess administrative fines and issue orders of abatement to any unlicensed entity who engages in any action that requires licensure under the jurisdiction of the Board, not to exceed $5,000 for each occurrence pursuant to a citation issued by the Board.

M/S: Oh/Patel

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

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Barker	Yes
Cameron-Banks	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes

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

Chairperson Serpa advised as part of the October Enforcement and Compounding Committee, members consider recently signed legislation and discussion implementation.

a. Assembly Bill 852 (Wood) Health Care Practitioners: Electronic Prescribing

Chairperson Serpa advised Assembly Bill 852 which was signed by the governor on September 25, 2022. Dr. Serpa reported this measure makes several changes to the e-prescribing requirements in California. Changes include authority for

pharmacies, pharmacists, and authorized practitioners to decline to dispense or furnish based on an electronic prescription submitted via software that does not meet specified requirements. The measure creates additional exemptions from electronic prescriptions as specified and exempts the prescription transfer requirements under specified conditions. In addition, it requires a prescriber to register with the Board and state they meet one or more of the specified criteria for exemption. Such registration is required on an annual basis.

Chairperson Serpa referenced meeting materials that include staff recommendations for implementation. Dr. Serpa noted implementation will include education of the changes as well as additional activities related to the online registration. Specifically related to the online registration, staff suggested that implementation be substantially like the online registration process used for drug-take back locations or the Board's health services registry. Dr. Serpa noted staff proposed that the online registry would include the prescriber's name, license number, email address, and exemptions being claimed. Dr. Serpa noted except for the email address, this information will be posted and available on the Board's website. Dr. Serpa added as annual registration is required, it is recommended that the annual registration occur consistent with the calendar year. Dr. Serpa provided the prescriber's email address will be used to facilitate the reminder.

Chairperson Serpa noted her understanding that both the Medical Board and Board of Registered Nursing have advised Board staff they are comfortable with this implementation approach. Dr. Serpa added the Medical Board has also recommended that, if possible, a hyperlink to the prescriber's license lookup be included. Dr. Serpa stated she was comfortable with the approach offered and appreciated member comments.

Members were provided the opportunity to comment. Member Oh agreed with Chairperson Serpa and the implementation efforts recommended.

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

Chairperson Serpa requested staff confirm with counsel that the Board does not need to develop regulations in this area; however, should regulations be required, Dr. Serpa requested Board staff prepare draft language for consideration at the next meeting that could be used to facilitate this implementation.

b. Assembly Bill 2194 (Ward) Pharmacists and Technicians; Continuing Education Cultural Competency

Chairperson Serpa advised Assembly Bill 2194 was approved by the governor on September 30, 2022. Dr. Serpa noted this measure requires that, effective January 1, 2024, pharmacists and pharmacy technicians must complete at least a one-hour course in cultural competency during the two years preceding the renewal application period. Dr. Serpa added the measure would prohibit the Board from renewing a pharmacist or pharmacy technician license unless the individual has completed the course.

Chairperson Serpa provided implementation for this measure would primarily involve developing a system for establishing a renewal process that includes continuing education requirements for pharmacy technicians. Dr. Serpa noted as part of the implementation the Board would need to establish a records retention period. Dr. Serpa added it appeared appropriate to mirror the requirements for pharmacists, which require maintenance of records for four years. Dr. Serpa noted staff suggested that implementation of the provisions include amendments to existing CCR section 1732.5 to update the renewal requirements for pharmacists.

Chairperson Serpa noted as indicated in the meeting materials the Board previously recommended changes to 1732.5 to consolidate all CE related requirements for pharmacists into a single regulation to assist pharmacists with compliance. However, after that action, staff was advised that such an approach may not be appropriate. At that time, giving the pending legislation, it was recommended that the two issues be considered together if AB 2194 is enacted.

Chairperson Serpa agreed with the staff suggestion that discussion should also resume regarding the larger policy goal to determine what, if any, additional amendments to the section would be appropriate to further the Board's policy goal related to all continuing education requirements for pharmacists. Dr. Serpa added staff would also evaluate the potential to update online, and system generated renewal notices to determine if updates can be made in advance of the effective date.

Chairperson Serpa advised education on the changes in the law would also be included in the Board's newsletter, online resources, and Board-provided CE on pharmacy law. Dr. Serpa agreed with the implementation approach detailed in the meeting materials and suggested implementation efforts moving forward be developed by the Licensing Committee.

Members were provided the opportunity to comment. Members agreed with the consolidation and development by the Licensing Committee.

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

c. Senate Bill 731 (Durazo) Criminal Records: Relief

Chairperson Serpa advised Senate Bill 731 was approved by the governor on September 29, 2022. Dr. Serpa noted this measure expands automatic relief to include arrests for felonies punishable by state prison and added the measure would expand automatic relief to certain criminal felonies committed after January 1, 2005, under specified conditions. Dr. Serpa reported implementation would require staff to review relief notifications to determine what if any action is necessary and staff would also work with the Attorney General's Office to determine any potential impact on pending matters.

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

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

d. Senate Bill 872 (Dodd, Chapter 220, Statutes of 2022) Pharmacies: Mobile Units

Chairperson Serpa advised Senate Bill 872 was chaptered on August 29, 2022. Dr. Serpa noted this measure allows a county, city and county, or special hospital authority to operate a mobile unit as an extension of the pharmacy license held. Dr. Serpa noted the measure authorizes the mobile unit to dispense prescription medications under specified conditions and requires notification to the Board 30 days prior to commencing use as well as 30 days prior to discontinuing use of a mobile unit.

Chairperson Serpa agreed with the staff recommendation to develop a standardized notification process. Dr. Serpa noted during prior Board discussions of the measure, the Board noted the need to develop FAQs. Dr. Serpa reported the FAQs would include among other items, direction on operational issues including provisions for pharmacist breaks and lunches, security of the mobile unit during such periods, and the notification process. Dr. Serpa advised while development of the FAQs will be completed by the Communication and Public Education Committee, Dr. Serpa believed it would be appropriate for the Enforcement and Compounding Committee to consider if additional items are appropriate for inclusion in the FAQs.

Members were provided the opportunity to comment. Member Barker inquired about drug storage or security while the mobile units are in use. Dr. Serpa noted

the security and storage of drugs in the mobile unit during operation would be included in the FAQs.

Members of the public were provided the opportunity to provide public comment. Public comment suggested that security needs to be addressed and noted that the issue of who maintains the keys, etc.

e. Senate Bill 988 (Chapter 988, Statutes of 2022) Compassionate Access to Medical Cannabis Act or Ryan's Law

Chairperson Serpa reported Senate Bill 988 was approved by the governor on September 2, 2022, noting the measure repeals the problematic requirement that a hospital manage a terminal patient's personal use of medical cannabis in the same manner as Schedule II-IV drugs. Dr. Serpa advised implementation was straightforward and would include education on the changes in the law in the Board's newsletter, online resources, and Board-provided CE on pharmacy law.

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

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

f. Senate Bill 1346 (Becker) Surplus Medication Collection and Distribution

Chairperson Serpa reported Senate Bill 1346 was approved by the governor on September 30, 2022. Dr. Serpa added the measure related to surplus medication collection and distribution programs expands the entities that are eligible to donate medications to a county operating such a program. Dr. Serpa noted the measure also establishes pilot programs in specified counties to allow for the expansion of county run programs. The measure requires the Board to evaluate the pilot program and prepare a report to the Legislature on January 1, 2028. Dr. Serpa believed implementation activities detailed in the meeting materials are appropriate including receiving updates on the staff's assessment of the program assuming identified resources are received. Dr. Serpa believed annual updates on the program would be appropriate and believed they should begin as part of the July 2024 Committee meeting. Dr. Serpa added this will provide staff the opportunity to secure resources and begin the evaluation process. Dr. Serpa noted additional Implementation will include education on the changes in the law in the Board's newsletter, online resources, and board provided CE on pharmacy law.

Members were provided the opportunity to comment including the frequency of updates to monitor implementation of the pilot programs.; however, no comments were provided.

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

VIII. Review and Discussion of Enforcement Statistics

Chairperson Serpa advised meeting materials included enforcement statistics reflecting enforcement related activities between July 1 and September 26, 2022. Dr. Serpa noted as indicated in the meeting materials, the Board received 848 complaints during this period and closed 614 investigations. Additionally, the Board secured two interim suspensions orders and one penal code 23 restriction. Dr. Serpa noted as of September 26, the Board had 1,404 field investigations pending with the average days for various stages of the investigation process included in the meeting materials.

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

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

IX. Future Committee Meeting Dates

Chairperson Serpa reminded participants that the October 19, 2022, Committee meeting was cancelled noting the meeting was originally scheduled in anticipation of USP releasing its finalized revised compounding chapters 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. Dr. Serpa advised the Board will continue to monitor for updates from the USP and will keep members apprised of potential impacts to the Committee's meeting schedule. Chairperson Serpa advised the next Committee meetings dates were:

- January 23, 2023
- April 13, 2023
- July 18, 2023
- October 12, 2023

XII. Adjournment

The meeting adjourned at 9:50 a.m.