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:	November 5, 2019
LOCATION:	Board of Pharmacy 2720 Gateway Oaks Drive, Suite 105 Sacramento, CA 95833
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Maria Serpa, Licensee, Vice-Chair Greg Lippe, Public Member Ricardo Sanchez, Public Member Albert Wong, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Laura Freedman, DCA Staff Counsel MaryJo Tobola, Senior Enforcement Manager Debbie Damoth, Administration Manager

1. **Call to Order and Establishment of Quorum**
   Chairperson Allen Schaad called the meeting to order at 9:43 a.m. A quorum was established.

2. **Public Comment on Items Not on the Agenda, Matters for Future Meetings**
   Chairperson Schaad invited public comment. Additionally, he stated the committee will resume its discussion of the development of an alternate Enforcement Model and will continue review of Disciplinary Guidelines at the next committee meeting.

   No public comment was received.

3. **Approval of the July 10, 2019 Enforcement Committee Minutes**
   Chairperson Schaad requested approval of the minutes from the July 10, 2019, Enforcement Committee meeting.

   Motion: Approve the minutes.
   M/S: Sanchez/Lippe
   Support: 4 Oppose: 0 Abstain: 1

4. Discussion and Consideration of Post Implementation Review of Inventory Reconciliation Requirements for Controlled Substances, Including Discussion and Consideration of Possible Amendments to Title 16, California Code of Regulations Section 1715.65

Chairperson Schaad provided relevant law and background. He stated CCR Section 1715.65 establishes the board's requirements for pharmacies and clinics to perform inventory reconciliation activities to detect and prevent the loss of controlled substances.

Further, following adoption of the regulation, in order to provide guidance to the regulated public, the board developed and posted answers to frequently asked questions on the board's website.

During its last meeting, the committee discussed the regulation and noted that it may be appropriate to provide clarification in the regulation through amendments to the language. Some of the areas for clarification included the potential need to clarify the requirements for automated drug delivery systems (ADDS) used in hospitals and the definition of satellite locations. The committee received public comment requesting that the board clarify the term "periodic" and sought alternative solutions to maintaining signatures for individuals performing inventory counts.

For committee discussion, Chairperson Schaad informed the committee that he has worked with staff and counsel to draft possible amendments to the current regulation. As drafted, the regulation language would clarify the frequency for completion of the reconciliation report for Schedule III-V medications. Further, it will allow individuals performing counts to sign and date documentation of the count as opposed to the report itself. The draft language defines the satellite location and clarifies that a physical count is not required for inventory of an ADDS in specified locations; however, all other reporting requirements must be completed. The proposed language was provided in Attachment 2.

As part of the public discussion, California Pharmacists Association (CPhA) representative, Danny Martinez, sought clarification on who should sign under subsection(e). Ms. Sodergren clarified that the person responsible for the operation of a clinic is the person who will sign the verification of the inventory reconciliation report.

Additionally, as part of public comment, CVS Health Representative, Mark Johnston, inquired about adding schedule III - V substances to the inventory report instead of inventory functions. He urged the committee to take into consideration the financial impact of adding CIII-V into the report, especially to smaller pharmacies.

Albert Wong suggested that in order to track large losses, inventory reports should be submitted directly to the board, rather than just be maintained at the pharmacies. Chairperson Schaad stated the submission of reports directly to the board could be discussed by the board at the next meeting. A member of the public also suggested the DEA's automated comprehensive drug reporting system, ARCOS, could be used to provide some inventory data to the board.

Ms. Serpa encouraged the public to review the board's FAQ in order to address concerns regarding the "end disposition" of medications. She further clarified, the process ends when the patient receives the medication.

A member of the public asked where the end point is when medication is being dispensed by an anesthesiologist. Ms. Serpa stated, this requirement is a snapshot of the medications that are under the purview of the pharmacy at the beginning and at the end, that snapshot may include anesthesia kits or use of anesthesia medications (i.e. the removal of medication from a PIXAS machine) or some unusual locations like transport kits.

Ms. Sodergren and DCA Legal Counsel, Laura Freedman, confirmed that the regulation states the individual(s) performing the inventory count also need to be identified and they need to sign and date the document.

Ms. Freedman expressed concerns regarding capturing language in the regulatory language that specified policy direction, specifically in the area of end disposition. She recommended that the committee allow the executive officer to work with the committee chair and legal counsel to clarify regulatory language.

Motion: Forward amendments to Section 1715.65 to the board to consider the language and initiate rulemaking and delegate authority to the Executive Officer to work with Committee Chair and DCA Counsel to make some language changes that might further clarify the board's policy direction.
M/S: Lippe/Wong
Support: 5 Oppose: 0 Abstain: 0

5. **Discussion and Consideration of Proposed Amendments to Title 16, California Code of Regulations, Section 1715.6 Relating to Reporting Drugs Losses**

Chairperson Schaad stated the board requires any drug loss to be reported; however, under federal law, the DEA only requires the reporting of a significant drug losses. The board has discussed this issue in the past and detailed the challenges with taking a similar approach to DEA regarding reporting losses. Most notably, the board has received previous advice that such a change could not be implemented because of the requirements of the Administrative Procedures Act. During the last meeting, the board reviewed drug loss data and discussed the possibility of establishing a different threshold for reporting of drug losses.

The committee provided direction to staff and counsel on suggested language to establish threshold reporting requirements. The proposed amendments for the committee's discussion and consideration were provided as an Attachment 3.

As part of public comment, a CSHP representative recommended specificity when asking for "doses" since doses and quantities are two separate concepts; he suggested a more permanent clarification in regulation rather than in an FAQ. Additionally, a CVS representative

asked the following questions: Regarding "quantities", what is the delineation to get to the minimum amounts? The word substantial is used but is not defined; the DEA uses "significant", is it the same? Should it be in harmony with Federal requirements? Should the same word be used so there is consistency?

Due to the significant concerns raised, Chairperson Schaad agreed that further discussion and consideration of these amendments were necessary. Mr. Schaad recommended that board staff work with the Chair and consider comments to make further amendments to the regulation.

The committee adjourned for break at 10:36 A.M. and returned at 10:48 A.M.

6. **SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure and Postexposure Prophylaxis**

Chairperson Schaad provided relevant law and background. He stated this measure establishes authority for a pharmacist to furnish HIV preexposure prophylaxis and HIV postexposure prophylaxis under specified conditions. The provisions of the bill will need to have emergency regulations in place by July 1, 2020. Areas for regulation will cover training program requirements and, if new drugs come to market, regulations that identify the additional products that a pharmacist may furnish under the authority established. The language of the measure was included in Attachment 9.

Given the significance of this legislation, Chairperson Schaad suggested the committee recommend the Communication and Public Education committee consider an education campaign for both consumers as well as pharmacists. Also, he suggested that the committee discuss whether the development of regulations should be completed under the auspices of the Licensing Committee. He believed it would be necessary to consider proposed emergency regulations as part of the January Board Meeting. The regulations must be developed with the Medical Board, and board staff will need to coordinate efforts with the Medical Board, Office of Aids, and other stakeholders.

James Gaspar of the Department of Health Care Services offered the department's expertise in developing the regulations and training in collaboration with CDPH and DCFS.

Krista Pfefferkorn, Chief of Staff from the office of Senator Scott Wiener, presented a statement from Senator Weiner briefly outlining the intent of his sponsored legislation, as well as his gratitude and support for the board's efforts.

A representative of the San Francisco Aids Foundation, co-sponsors of SB 159, asked that the committee enforce implementation of SB 159 to ensure participation of pharmacies across the state especially in the more rural areas, which are a critical in the successful implementation of this bill.

Steve Gray of CSHP offered support in developing training programs with institutions and in underserved areas.

Michelle Rivas, Vice President of CPhA Center for Advocacy, expressed CPhA's support of SB 159 and introduced Dr. Maria Lopez of Mission Wellness Pharmacy in San Francisco. Dr. Lopez expressed her support and shared her availability to provide her experiences for the development of the implementation plan of SB 159 into the community pharmacies. Dr. Lopez also informed the board that the State of Washington has a similar program and they are the first published study completed on PREP. Dr. Lopez offered to share her information with the committee to assist in the development of regulations.

Motion: Forward to Licensing Committee or Legislation and Regulation Committee for the development of regulations.
M/S: Lippe/Sanchez
Support: 5 Oppose: 0 Abstain: 0

7. <u>Discussion and Consideration of Recently Enacted Legislation Impacting the Practice of Pharmacy</u>

a. <u>AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database</u>
Chairperson Schaad provided relevant law and background. He stated effective January 1, 2021, AB 528 expands the CURES reporting requirements to also include Schedule V drugs and would reduce the reporting requirement to CURES to within one business day from the date the prescription was released to the patient.

Additionally, AB 528 requires reporting to the CURES system by veterinarians as soon as reasonably possible, but not more than seven days after dispensing, allows physicians that do not possess a DEA registration to enroll in the CURES system, and expands the delegate provisions for individuals working under a prescriber to retrieve data from CURES.

Pursuant to public comment, the board will ensure information about the new requirements are included in the newsletter as well as incorporated into the board's webinar training.

b. <u>AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications</u>
Chairperson Schaad provided relevant law and background. He stated, effective immediately, this measure creates a limited exemption to the licensure transferability requirements for a pharmacy to relocate because of damage caused by a declared disaster. Further the requirements for a pharmacy technician working in a remote dispensing site pharmacy are established. Specifically, to qualify to work in such a location a pharmacy technician must satisfy the following conditions:
- Possess a pharmacy technician license that is in good standing.
- Possess and maintain a certification issued by a board-approved pharmacy technician certification program.
- Possess one of the following:

- A minimum of an associate degree in pharmacy technology.
- A minimum of a bachelor's degree in any subject.
- A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.

- Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

Board staff will need to establish a streamlined process for pharmacies to follow when relocation is allowed under the provisions of the bill. In addition, with the technician requirements now finalized, staff will post the application and requirements for entities seeking licensure as a remote dispensing site pharmacy. A copy of AB 690 was provided as Attachment 6.

Ms. Sodergren stated that the board had initiated regulations to establish requirements for a pharmacy technician based on statutes that were in place several years ago, the board will now withdraw its regulations as no longer necessary given the new statute.

As part of public comment, remarks were made suggesting the use of a signed affidavit to confirm licensure given that the law is effective immediately.

In response to a question regarding the application and requirements for entities seeking licensure as a remote dispensing site pharmacy, Ms. Sodergren stated that there is a draft application in the process of being submitted for legal review.

Motion: Recommendation to accept a signed affidavit documenting the pharmacy technician's qualifications and experience as part of the application.
M/S: Lippe/Sanchez
Support: 5 Oppose: 0 Abstain: 0

c. <u>AB 973 (Irwin, Chapter 184, Statutes of 2019) Pharmacies: Compounding</u>
Chairperson Schaad provided relevant law and background. He stated, Effective January 1, 2020, this measure explicitly states that compounding of drug preparations by a pharmacy must be done consistent with the relevant compounding chapters of the United States Pharmacopeia-National Formulary.

Additionally, the new provision will augment the board's compounding regulations and Business and Professions Code section 4342 which cites the board's authority to institute any action it deems necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform with the standard and tests as to quality and strength, provided in latest edition of the USP.

Mr. Schaad clarified, where there is a discrepancy between the standards and the board's regulations, the most stringent requirement applies. He provided the measure's language in Attachment 7.

d. AB 1723 (Wood, Chapter 323, Statutes of 2019) Clinics: Purchasing Drugs at Wholesale
Chairperson Schaad provided relevant law and background. He stated, effective January 1, 2020, this measure will conform the maximum hours of operation (increasing from 20 to 40 hours) for a primary care community or free clinic with the provisions of HSC 1206. AB 1723 is a technical cleanup measure.

No public comment was received.

e. SB 569 (Stone, Chapter 705, Statutes of 2019) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency
Chairperson Schaad provided relevant law and background. He stated, effective January 1, 2020, this measure allows a pharmacist to fill a prescription for a controlled substance that does not conform to the controlled substances security form requirements under the following conditions:

1. The prescription form indicates that the patient is affected by a declared emergency.
2. The prescription is written and dispensed within first two weeks of a notice issued by the board.
3. The pharmacist exercises appropriate professional judgement including reviewing the CURES system prior to dispensing.
4. Limits the dispensing of a Schedule II to no greater than a seven-day supply.
5. Requires confirmation that the patient is otherwise unable to access medications. Verification of residency within an evacuation area is one acceptable form of confirmation.
6. Prohibits the refill of a prescription dispensed under these provisions.

The board routinely issues a Subscriber Alert when a declared disaster declaration is made. Staff believes this alert can serve as the notice required to be issued by the board. The committee may wish to provide guidance on documentation pharmacies may wish to maintain to confirm compliance with the provisions. For example, it may be appropriate to document either on the prescription or other pharmacy records that the confirmation of the patient's residence was completed.

President Lippe asked what would be done if an emergency lasts more than seven days. Ms. Sodergren informed that the legislation limits Scheduled II's to a seven-day supply; it can not be changed.

Steve Gray of CSHP encouraged the board to provide guidance to the pharmacies. He stated, considering the opioid epidemic, pharmacists are very nervous to do anything outside of normal practice when it comes to controlled substances. The guidance would help pharmacies determine what they can do during an emergency. He encouraged the board to be aware of any confusion that might come up with emergency refills.

Ms. Sodergren stated that a newsletter article will be published which will detail out the different provisions allowed. The article will also be made available on the board website.

Motion: Direct staff to work with the committee chair in drafting pharmacy guidance to confirm compliance with the provisions.
M/S: Lippe/Sanchez
Support: 5 Oppose: 0 Abstain: 0

f. SB 655 (Roth, Chapter 213, Statutes of 2019) Pharmacy

Chairperson Schaad provided relevant law and background. He stated, effective January 1, 2020, this measure makes several technical and other conforming changes to Pharmacy Law.

1. Increases the number of hours of an externship for a pharmacy technician trainee to 340 hours including rotations between community and hospital pharmacy. Further increases the number of participation hours for the trainee to no more than 140 hours at a specific location.
2. Allows a licensed reverse distributor to acquire drugs from an unlicensed source that was previously licensed.
3. Specifies that an examination score on the CPJE or NAPLEX is valid for purposes of licensure for no more than one year following replacement with another occupational analysis. Further, creates an exemption for the NAPLEX examination if the applicant holds an active license in another state or territory.
4. Modifies the advanced practice pharmacist renewal requirements to allow the board to inactivate the APH license under the following conditions:
    a. The pharmacist license becomes inactive.
    b. The APH fails to provide documentation of the completion of the required CE.
    c. The APH fails to provide documentation of completion of CE as part of an audit or investigation.

Chairperson Schaad stated that the following year, effective July 1, 2021 requires application and renewal payments for government owned applicants and licensees.

There were no public comments.

8. Presentation on Routine Pharmacy Inspections

Chairperson Schaad introduced Julia Ansel and Tom Lenox who provided a presentation on routine pharmacy inspections, including statistics and outcomes. He informed the committee the board's goal is to complete routine inspections of all pharmacies at least every four years. As of the end of September, the board had over 6,500 licensed community pharmacies. As part of the Enforcement Committee's discussion on April 3, 2018, regarding the board's Enforcement Program, the committee and board staff discussed issues pertaining to the implementation of routine inspections beginning May 2018 and the proactive effect that could result from an increased number of routine inspections. Additionally, the committee's strategic goal is for a routine inspection to be completed once every four years in every facility with a pharmacy license. In fiscal year 2018/19, board inspection staff was assigned routine inspections in addition to their normal workload to assist in achieving this goal. The purpose of routine inspections is to educate pharmacies on compliance issues and provide information on new laws and regulations that effect the practice of pharmacy.

Ms. Ansel and Mr. Lenox provided general information on board inspections during FY 18/19.

9. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad provided enforcement statistics for the first three months of the 2019/20 fiscal year.

Chairperson Schaad stated that a review of workload statistics for the past year indicates a 14% decrease in the number of compliant investigations closed; 5% increase in the number of case investigations pending; a 37% decrease in the average number of days for an investigation, and a 12.5% increase in the number citations issued with an order of abatement. Additionally, administrative case outcomes have increased by 26% and the issuance of public protection sanctions has increased by 100%.

The board currently has 1,724 field investigations pending as of October 1, 2019. Below is a breakdown providing more detail:

- 107 cases under review for assignment, averaging 11 days
- 938 cases under investigation, averaging 178 days
- 297 investigations under supervisor review, averaging 86 days
- 127 investigations under second level review, averaging 53 days
- 255 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 49 days.

10. Future Committee Meeting Dates

The next Enforcement Committee meeting is scheduled for January 29, 2020.

11. Adjournment

The meeting was adjourned at 11:55 a.m.