California State Board of Pharmacy
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ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: September 14, 2018

LOCATION: California Board of Accountancy
4th Floor Conference Room
2450 Venture Oaks Way
Sacramento, CA 95833

COMMITTEE MEMBERS PRESENT: Allen Schaad, Licensee Member, Chair
Albert Wong, Licensee Member, Vice Chair
Victor Law, Licensee Member
Gregory Lippe, Public Member
Ricardo Sanchez, Public Member
Stan Weisser, Licensee Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General
Laura Hendricks, Staff Analyst
MaryJo Tobola, Senior Enforcement Manager

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

Chairperson Allen Schaad called the meeting to order at 9:31 a.m. A quorum was established.

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

Member of the Public, Dr. Gray, asked the committee to consider a discussion on the new laws going into effect and how they will be enforced. Dr. Gray noted that some legislation creates new requirements and it would be helpful to have policy discussions on how the board intends to enforce these new requirements. Dr. Gray also noted that there is also a need to discuss the standard of care for pharmacists that are providing pain management.

Chairperson Schaad noted that it would fall under the strategic goal 2.3 relating to improved education.

Member of the Public, Ms. Talley, requested that the committee discuss the term "significant loss." She requested that the committee discuss a statutory change.

3. Update on the University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Chairperson Schaad stated that at the July 2017 Board Meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. Chairperson Schaad explained that this study involves a waiver of California Code of Regulations Title 16, section 1713, in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter but is installed in a hospital location.

Chairperson Schaad informed the committee that during the July Board Meeting, the board heard the final report of this study and supported a request from UCSD to extend the study for one year to provide additional data regarding the study and time for the board to consider a regulation modification involving ADDS to provide medication to patients.

Additionally, during the November 2017 Board Meeting, the board considered further updates to the study as well as a recommendation to modify the parameters of the study as detailed below:

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

Chairperson Schaad stated that ultimately the board voted to both expand the study as well as extend it. During that meeting the board also directed UCSD to provide study updates to the Enforcement Committee every six months. This report to the committee is to fulfil this requirement.

Chairperson Schaad informed the committee that for today's discussion the committee will have the opportunity to review a written update provided by UCSD on the progress and findings of the study. No formal presentation will be provided, but representatives of the study will be available to respond to committee member questions.

Ms. Herold informed the committee that the next UCSD presentation is scheduled for March 2019.

Ms. Herold reminded the committee that the board had requested a data comparison of people who received truly new prescriptions versus those who were getting refills. Due to the reported difficulty in collecting this data, Ms. Herold asked the committee if they still wanted UCSD

researchers to continue this collection of data. The committee opted to discontinue collection of this data category.

Motion: Direct UCSD to discontinue the collection of Truly New Prescription data.

M/S: Lippe/Sanchez

Support 6 Oppose: 0 Abstain:0

4. Presentation on the Board's Enforcement Program

Anne Sodergren provided an overview of the board's enforcement program. The presentation provided general workload and staffing information.

Committee discussion included the possible referral of employee pilferage cases for criminal prosecution. Ms. Sodergren reminded the committee that both the Enforcement Committee and the board has previously considered whether to adopt a policy to require pharmacies to always report to law enforcement agencies, the policy decision at that time was to not require such reporting.

Ms. Sodergren informed the committee that the board staff are collecting information specific to drug loss reports and whether law enforcement agencies are notified by the pharmacy. Once that data set is obtained the board would like the opportunity to review and determine whether it is practice to notify law enforcement at that time that they determine employee pilferage. This data analysis would provide information on how integrated that practice is and whether a policy should be reconsidered. Additionally, Script articles could be published to recommend law enforcement notification.

As part of the public discussion, clarification was sought on what information is reported to the National Practitioner Data Bank (NPDB) and when is it reported. Board staff advised that disciplinary information is required to be reported to NPDB by Federal Law. Subsequently, once there is a change in the status of a license, for example once a licensee has completed probation, a follow up report is submitted to NPDB to inform them of the completed probation.

5. Presentation on Enforcement Trends

Ms. Herold provided the committee with a presentation on compounding enforcement trends. Aggregate data on the outcomes of sterile and non-sterile pharmacy inspections conducted in 2017/18 as well as the top violations found in each setting were provided for the committee's review and discussion.

Ms. Sodergren provided the committee with a presentation on drug loss enforcement trends. The committee was provided with summary data from a review of drug loss reports submitted over the last three fiscal years for the committee's review and discussion. The statistics reveal that the number of drug loss reports submitted has increased 153 percent. Furthermore, the total dosage units reported as lost also increased, but at a much smaller rate of 16 percent.

Ms. Sodergren suggested that a follow-up presentation, to drug loss enforcement trends, could be provided to the committee yearly.

As part of the committee's discussion on drug losses it was suggested that pharmacies may want to consider transitioning to a more real-time inventory for controlled drugs to reduce the stock on hand. Such a change could reduce the number of robberies and night break ins.

Further the committee noted that as the Inventory Reconciliation regulations take effect, it is expected that losses due to employee pilferage will also be reduced as identification of the losses should have more quickly.

6. Presentation and Discussion on Efforts to Reduce Investigation Times and Case Resolutions

Chiefs of Enforcement, Julia Ansel and Tom Lenox provided a presentation of the board's current pending investigations, including the average days by the identified benchmarks as of August 1, 2018.

The committee was informed that DCA's target for Intake, which is defined as the number of days from receipt of the complaint receipt to the date the complaint is either closed or assigned to an investigator; DCA's target average is 20 days. The Board of Pharmacy's average Intake for FY 2017-18 for field investigations was 27 days, compared to the improved 19 days for the month of July 2018.

In addition, the committee was informed that the average days for cases under investigation in the field during FY 2017-18 was 235 days compared to the improved 165 days for the month of July 2018.

The committee was informed that DCA's target for case investigations, not transmitted to the Office of the Attorney General, is 210 days, which includes both intake and investigation.

Public comment included a recommendation that the board establish a sub-committee that would evaluate each case before being referred to the Office of the Attorney General. It was suggested that such a committee could include a peer review by an independent expert and provide active board member input during the AG referral consideration process.

Chairperson Schaad agreed to discuss this referral issue during a future committee meeting.

The committee was released for lunch at 12:35 p.m. and reconvened at 1:19 p.m.

7. Discussion and Consideration of the Board's Citation and Fine Program

Chairperson Schaad stated that the board has asked staff to provide information regarding board-issued citations and fines.

Ms. Ansel and Mr. Lenox provided a snap shot of data from board issued citations for the month of

July 2018. The presentation revealed 279 violations, with an average fine amount of $608 per violation, for a total of $169,500 in fines assessed in the month of July. In addition, they reviewed the top citation violations issued for the month. Citations examples were provided to the committee which included various violations including medication errors, failure to provide documentation substantiating continuing education completion, unprofessional conduct, pharmacy security/ drug loss, duty to review drug therapy and compounding policy and procedures requirements. Ms. Ansel and Mr. Lenox commented that board staff has been reviewing citations for opportunities where abatements might be offered. Specifically, with some citations there may be instances where the licensee may have the option to take continuing education in a specific area of pharmacy law or education and upon proof of completion, the fine associated with the citation may be reduced or eliminated, depending on the circumstances of the case

Public discussion included a request for clarification on what constitutes unlicensed practice and who determines the amount of citations and fines within the board. Ms. Herold provided examples of unlicensed practice. Mr. Lenox confirmed that the Chiefs of Enforcement review and approve citations and fines issued as a result of inspections and investigations.

8. <u>Discussion and Consideration of Convening Administrative Case Hearings Before Board Members</u>

Chairperson Schaad informed the committee that Government Code (GC) section 11517 establishes the requirements for adjudication of contested cases before an Administrative Law Judge (ALJ) or before an agency itself.

Chairperson Schaad explained that although the law allows for two different adjudication processes, the board's administrative case hearings are currently only heard before an ALJ. Alternatively, at the discretion of the agency, GC section 11517 also allows that an administrative case hearing may be heard by the agency itself with an administrative law judge presiding over the proceeding. This is similar to the method used by the board to consider petitions for modification to penalties.

Chairperson Schaad highlighted that under this second construct all of the following conditions must be in place if a contested case is heard before an agency itself, all of the following provisions must apply:

(1) An ALJ shall be present during the consideration of the case and, if requested, shall assist and advise the agency in the conduct of the hearing.
(2) No member of the agency who did not hear the evidence shall vote on the decision.
(3) The agency shall issue its decision within 100 days of the submission of the case.

Chairperson Schaad stated that during the June 2018 committee meeting, board members were informed that pharmacy boards in other states have opted for administrative case hearings to be heard with board members.

Chairperson Schaad suggested that while discussing this issue the committee may wish to take into consideration that in FY 17-18, 42 proposed decisions were received from ALJs. That equated to 62 days of hearings. Although the majority of cases heard before an ALJ are one day, as case

complexity increases so do the number of hearing days, which are typically consecutive days.

Chairperson Schaad presented questions and areas of concerns the committee may wish to consider include:

- What is the purpose of eliminating the ALJ hearing?
- Determine what, if any, challenges exist with the current process of adjudication of contested cases.
- Would eliminating the ALJ hearing the case remove significant delays in the administrative case process?
- Discuss the consequences and/or challenges of a contested case being heard by the agency itself.
- What parameters would the board use to determine if a case is to be heard before the board or before an ALJ alone?
- Would it be possible for board members to absorb this additional time and resource commitment?

Additionally, Chairperson Schaad stated that last fiscal year either the full board or a committee of the board convened meetings on 25 days.

The board members discussed areas of potential concern. No action was taken regarding disciplinary case adjudication.

9. <u>Presentation on the Board's Inventory Reconciliation Process and Review of Frequently Asked Questions</u>

Chairperson Schaad provided background information which clarified that Title 16, California Code of Regulations (CCR) section 1715.65 requires that every pharmacy and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

Chairperson Schaad informed the committee that on April 1, 2018, a new board regulation took effect – California Code of Regulations, Title 16, section 1715.65. The board believes this regulation will aid pharmacies and clinics in preventing losses of controlled drugs and identifying losses early.

In order to clarify, Chairperson Schaad stated that the board asked staff to provide information about the new reconciliation regulation. Board supervising inspector Michael Ignacio and Chief of Enforcement, Tom Lenox provided general information on the board's inventory reconciliation process and frequently asked questions.

Chairperson Schaad informed the committee that since the adoption of the regulation, the executive officer and board inspectors have received numerous questions from licensees regarding the new reconciliation regulation. The board has focused on education to promote an understanding of the regulation. During this transition, inspectors will focus on the pharmacy's or clinic's good faith efforts to comply with the regulation.

In order to provide additional guidance to the regulated public, board staff worked with the DCA

counsel to draft FAQs. The first FAQ was made available on the board's website and was published in the July 2018 edition of The Script. A second FAQ is being developed based on interaction during inspections between inspectors and licensees. A copy of the first FAQ was provided.

Chairperson Schaad informed the committee that in addition, a presentation on the reconciliation regulation has been incorporated into the board's quarterly Pharmacist Drug Abuse and Diversion Training Program. It was presented to over 200 pharmacists at the July 28, 2018 event. The next event is scheduled for September 22, 2018. A copy of the presentation was also provided.

Ms. Herold informed the board that with the increased number of drug losses reported, it is expected that quantities reported will progressively decrease. Additionally, Ms. Herold encouraged that questions from the public should be forwarded to the board for future publications of FAQ sheets.

10. <u>Discussion and Consideration of Remodel Inspections of Sterile Compounding Pharmacies and Possible Authority to Assess a Fee for Such Inspections</u>

Chairperson Schaad provided relevant law and background information. Specifically, Business and Professions Code 4127.1 established the parameters of sterile compounding licensure requirements. Business and Professions Code section 4400(u) established the fees for issuance of sterile compounding licenses.

A Sterile compounding license shall not be issued or renewed until the location has been inspected by the board and found in compliance. A fee is assessed for the issuance or renewal of a sterile compounding license.

Chairperson Schaad stated that under current law, the board does not charge a fee for the remodel of sterile compounding pharmacy inspections. Since the beginning of fiscal year 2015/16, the board has conducted approximately 60 sterile compounding remodel inspections. Inspections are conducted by the board after a facility has remodeled their location. There is no requirement in the law for the board to conduct remodel inspections. Board staff believes that not conducting these remodel inspections could pose a patient safety risk. Remodel inspections are triggered by unforeseen damage, planned upgrades or expansion of a facility. The scope of a remodel includes simple projects to a full remodel or expansion. All sterile compounding inspections have the same requirements, to ensure full compliance with regulations adopted by the board.

When notified of a pending remodel to a sterile compounding facility, the board attempts to conduct an inspection within six to eight weeks from the date of notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. Travel costs and inspector time for remodel inspections are currently being absorbed by the board.

Chairperson Schaad informed the committee that for discussion and consideration the issue to consider is whether the board deems it appropriate to charge a fee for conducting sterile compounding remodel inspections.

Stan Weisser requested clarification on what constitutes a remodel and whether the board needs to redefine a remodel.

Public discussion included whether sterile compounding facilities should be required to pay fees for the inspecting remodeling that is necessary to maintain regulatory compliance and whether inspection fees would discourage licensees from improving their facilities.

Mr. Weisser motioned to have board staff establish an appropriate fee and conditions for remodel inspection for a sterile compounding licensing facility and delegate the committee chair to work with staff to refine the proposal. This motion was seconded by President Law.

After further discussion, it was recommended that this issue should be discussed and considered by the Licensing Committee. As a result, the motion introduced by Mr. Weisser was tabled.

MOTION: Move to table the motion to have board staff establish an appropriate fee and conditions for remodel inspection for a sterile compounding licensing facility and delegate committee chair to work with staff to refine the proposal.

M/S: Weisser/Lippe

Support: 6 Oppose: 0 Abstain: 0

MOTION: Move to refer this issue to the Licensing Committee.

M/S: Weisser/Lippe:

Support: 6 Oppose: 0 Abstain :0

11. Discussion and Consideration of Federal and State Law Regarding Cannabidiol

Chairperson Schaad stated that Supervising Deputy Attorney Joshua Room has written his opinion on the legal status of products containing cannabidiol (CBD), in light of the FDA approval of Epidiolex and AB 710 (Wood), which was enacted in mid-2018.

SDAG Room clarified that the opinion regards only the prescribing of products containing CBD not the selling of products. He informed the committee that currently Federal and State law has not changed in status for the purpose of prescribing or dispensing. In addition, the Federal Drug Enforcement Agency (DEA) has taken no action to reschedule CBD and there is no indication on their agency website that they will.

SDAG Room was asked what a pharmacist should do if he/she has knowledge that a patient is currently taking a product containing CBD, which may have negative interactions with medication being dispensed. SDAG room responded that a pharmacist is still responsible for consulting with the patient and informing the patient of the possible impact of the CBD product on their dispensed medication.

Public discussion, in part, included whether the board should partner with other agencies to discourage the sale of CBD products in non-pharmacy settings and advocate to reschedule CBD.

12. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad informed the committee that during the June 2018 committee meeting, members directed board staff to include the following data elements into the Enforcement Statistics: Proof of Abatements Requested, Average Investigation Times, Cease & Desist Orders, Unlicensed Activity.

Chairperson Schaad introduced for committee discussion and consideration the revised Enforcement Statistics for July 1 – August 31, 2018. Chairperson Schaad invited committee feedback on the revised format and new data elements.

No questions or comments were presented by the board.

13. Discussion and Consideration of Bifurcation of the Enforcement and Compounding Committees

Chairperson Schaad informed the committee that during its May 2018 board meeting, members voted to pursue a statutory proposal to incorporate USP compounding chapters into the board's requirements for compounding drug preparations. As part of its discussion, the board noted that two of the compounding chapters, <795> and <797>, are in the revision process by USP and USP <800> has been finalized but is not yet in effect.

Chairperson Schaad stated that subsequent to that meeting, in recognition of the large impending policy work that will be required, President Law has bifurcated that Enforcement and Compounding Committee into two committees. Chairperson Schaad provided the membership for the respective committees.

Enforcement Committee
Allen Schaad, Chair
Albert Wong, Vice-Chair
Victor Law
Greg Lippe
Ricardo Sanchez
Stan Weisser

Compounding Committee
Stan Weisser, Chair
Allen Schaad, Vice-Chair
Shirley Kim
Victor Law
Maria Serpa

Chairperson Schaad anticipates that the compounding committee will begin its work in early 2019. Proposed meeting dates for both committees will be provided during the meeting.

14. <u>Future Committee Meeting Dates</u>

Chairperson Schaad informed the committee that the Enforcement Committee will meet on December 13, 2018. A list of future meeting dates for 2019 was provided at the meeting.

Chairperson Schaad adjourned this meeting at 3:46 p.m.