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

DRAFT ENFORCEMENT COMMITTEE MEETING MINUTES

DATE:	January 29, 2020
LOCATION:	Embassy Suites by Hilton, Los Angeles-Glendale 800 North Central Avenue Glendale, CA 91203
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Maria Serpa, Licensee Member, Vice-Chair Greg Lippe, Public Member Ricardo Sanchez, Public Member Albert Wong, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Norine Marks, DCA Staff Counsel Ryan Greenlaw, DCA Staff Counsel Steve Pyun, Deputy Attorney General MaryJo Tobola, Senior Enforcement Manager Jennifer Niklas, Senior Admin. & Regulations Manager

1. **Call to Order and Establishment of Quorum**
   Chairperson Allen Schaad called the meeting to order at 9.05 a.m. Roll call was taken. A quorum was established.

2. **Public Comment on Items Not on the Agenda, Matters for Future Meetings**
   Chairperson Schaad invited public comment. There was no public comment.

3. **Approval of the November 5, 2019 Enforcement Committee Minutes**
   Chairperson Schaad requested the review and approval of the Minutes from the November 5, 2019 Enforcement Committee meeting.

   Motion: Approve the minutes, as is.
   M/S: Sanchez/Lippe
   Support:5 Oppose:0 Abstain:0

4. **Discussion and Consideration of Inventory Reconciliation and Report 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. Title 16, California Code of Regulations Section 1715.65 established the board's requirements for pharmacies and clinics to perform inventory reconciliation activities to detect and prevent the loss of controlled substances. He stated, during its last meeting the committee continued discussions on post implementation review of the board's inventory reconciliation regulation, noting that clarity was required in the regulation regarding the use of ADDS and the term satellite location. The committee sought to provide clarification on its expectations with respect to inventory reconciliation activities related to Schedule III – V medications. As part of its discussions, the committee was further asked to provide flexibility regarding signature requirements.

He stated, the committee offered amendments to the regulation for the board's consideration as part of its November 2019 meeting. Ultimately the board referred the matter back to the committee for additional consideration but released a policy statement regarding the inventory requirements for ADDS used in an inpatient hospital as well as clarity on the satellite pharmacy.

Chairperson Schaad stated, subsequent to the board meeting, and in consideration of comments received by the board and public, he worked with staff and counsel to draft possible amendments to the current regulation. As included in the proposal, an electronic signature provision was incorporated. Further, a more targeted approach was offered for drugs in other schedules. Specifically, included in the attached proposal, specified medication/strengths required inventory reconciliation reporting on an annual basis including:

- Alprazolam 1mg
- Alprazolam 2mg
- Tramadol 50mg
- Promethazine/Codeine 6.25mg/10mg

Chairperson Schaad provided a list of medications and the approximate number of dosage units reported as missing during the last fiscal year:

Alprazolam 1mg = 36,495
Alprazolam 2mg = 96,890
Tramadol 50mg = 29,546
Promethazine/Codeine (6.25mg/10mg) = 82,326

Chairperson Schaad stated that it may be appropriate for the committee to consider the revised proposal to determine if it addresses the board's concerns.

He provided attachment 2 which included a copy of the proposed language.

As part of public comments, a representative from Kaiser Permanente requested the committee harmonize this new regulation with existing regulations. The representative expressed concern regarding section (g), specifically the meaning of the term "separate". Additionally, he requested additional clarification to the existing FAQ. Committee Member

Serpa expressed support of providing clarification of the FAQ. A representative from CVS asked for clarification of the term "periodic". Additional public comment requested a correction for when a Pharmacist-in-Charge is changed, which schedules must be inventoried. Additionally, as part of public comment, there was concern regarding the signature requirement in section (e)(1). Committee Member Serpa agreed that section (e)(1) was unnecessary and supported the removal of that signature requirement.

In response, Executive Office (EO) Sodergren suggested further refining the proposed language based on the policy direction of the committee and presenting the updated language to the board tomorrow.

As part of public comment, the committee was informed about diversion of buprenorphine products. While buprenorphine products are considered Schedule III by DEA, California considers them Schedule V's. It was suggested that the committee might consider making buprenorphine one of the target drugs. Committee Member Serpa stated that she did not feel it was a good idea to hold up this proposed language approval for the addition of buprenorphine products.

Motion: Recommend the board approve the proposed amendment to Title 16 section 1715.65 Relating to the Inventory Reconciliation and Report Requirements for Controlled Substances and incorporate policy changes recommended by the committee. Delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

M/S: Sanchez/Lippe
Support:5 Oppose:0 Abstain:0

The committee took a break at 10:00 a.m. and returned at 10:22 a.m.

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

Chairperson Schaad provided relevant law and background. He stated, Title 16, CCR section 1715.6 currently states, "The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

Title 21, Code of Federal Regulations (CFR) 1301.76(b) states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft." Additionally, he provided, as part of past board discussions related to the board's new inventory reconciliation regulation, the issue of drug loss reporting requirements was mentioned and the difference between the Federal Code of Regulations requirements and California Code of Regulations. During the rulemaking process for the inventory reconciliation regulation, it was suggested that the board amend its current drug loss reporting requirement

(CCR 1715.6) to mirror the DEA requirements. At that time members were advised that such a change could not be implemented as the language lacked the necessary clarity required to comply with the Administrative Procedures Act.

Chairperson Schaad stated, over the last several meetings, the committee has considered drug loss information data reports, historical and current summary information. As indicated in the data, the number of drug loss reports received has more than doubled since FY 2015/16 and continues to increase. The data also reflected a significant decrease in the overall dosage units reported lost in the most recent fiscal year.

Chairperson Schaad reminded the committee, it discussed a draft proposal intended to modify the reporting requirements; however, after discussion, it was determined that additional consideration was necessary. Since that time, he met with staff and counsel to further evaluate the appropriate conditions under which a drug loss report should be filed with the board.

As reflected in the new proposal, additional forms of drugs were included to ensure more clarity was provided to the regulated public, while also ensuring professional judgement could be used for some reporting.

He provided attachment 3 included a copy of proposed draft amendments.

As part of the committee and public discussions the following suggestions were made: 1) in subsection (C) add "continuous infusions" and replace "multi-dose containers" with "units." 2) in subsection (C)(3) consider substituting "substantial" with "significant."

Motion: Recommend the board approve the committee's proposed amendment to Title 16, CCR, section 1715.6 related to the reporting of drug losses and policy changes. Delegate to the executive officer/counsel the authority to make any non-substantive and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

M/S: Lippe/Wong
Support:5 Oppose:0 Abstain:0

6. Discussion and Consideration of Legislative Proposal to Establish an Alternative Disciplinary Process

Chairperson Schaad provided relevant law and background. He stated, in general, the Administrative Procedures Act establishes the parameters for the disciplinary process. More specifically, Government Code section 11415.60 provides the authority for an agency to formulate and issue a decision by settlement pursuant to an agreement of the parties without conducting an adjudicative proceeding.

He briefed the committee, during the July 2019 Board Meeting, members expressed support of a framework developed and noted that additional refinement was completed by the committee.

Members were provided the opportunity to discuss the revised proposal to add Business and Professions Code section 4300.2. The model provided by Chairperson Schaad reflected the basic framework previously discussed by the committee and board, and incorporated additional procedural items as well as detailed the involvement of two board members as discussed by the board.

Chairperson Schaad informed the committee provided in attachment 4 was a framework of a draft statutory proposal intended to detail the basic tenets of the proposal as well as a letter from California Pharmacists Association (CPHA) regarding the board's initial proposal. Additionally, a copy of Government Code section 11425.10 which establishes the governing procedure by which an agency conducting adjudicative proceedings was provided.

Chairperson Schaad reviewed sections 1-10 of proposed section 4300.2 with the committee.

Initially, Danny Martinez of CPHA expressed overall support. Mr. Martinez asked whether the committee could prove a timeline of when a licensee could receive the findings of a violation. Chairperson Schaad expressed support for expeditious delivery of findings, but did not find it necessary to place a timeline into the proposed language.

As part of public discussion, there was concern regarding having only one licensee on the committee. Concern was based on doubt that the one professional would have enough professional knowledge of all licensing categories to make good decisions.

As part of the discussion DCA Legal Counsel, Norine Marks clarified that all mitigation and rehabilitation information would be presented to the committee and executive officer in writing, not in an oral conference format.

Danny Martinez of CPHA expressed concern stating that he assumed that the proposal included an oral conference opportunity for the licensee under section (4).

Chairperson Schaad and President Lippe stated their understanding that there was an oral conference component to this proposal, as well. Chairperson Schaad confirmed his current support of oral office conference component due to the complexity of the cases.

DCA Counsel Marks clarified an investigation would have been completed by a licensed pharmacist. Secondly, if there is no ability for the parties to arrive at a stipulated settlement it goes to hearing on an accusation and the burden is on the board to establish there is a basis for discipline.

Mr. Martinez opined, accusations are public record on the board website and consumers may already see that as a presumption of guilt or at least as negative. Mr. Martinez stated, additionally, when a licensee is given the findings, after the investigation has been completed and the findings are substantiated, significant time has passed yet there is still no opportunity at that point to say the investigation is incorrect.

Ms. Sodergren clarified, typically, if something is identified during an inspection, the violation is included in the inspection report and the licensees are issued an order of correction or a written notice of violation and asked to submit any additional information within 14 days.

Mr. Martinez requested that this agenda item be tabled to a future meeting. President Lippe supported the request to move this item to a future meeting.

A public member suggested a five-committee member panel. DCA Counsel Marks advised the committee a five-committee member panel may present quorum voting problems due to recusal issues.

EO Sodergren informed the committee there could not be negotiation outside of a meeting on this proposal. There could not be discussions outside this public meeting to decide on a compromise or decision to bring forward. The committee may request the chair to refine the proposal and bring the proposal to a future meeting, but all negotiations must be done in public in order to comply with the Open Meetings Act.

EO Sodergren suggested that if oral conferences are considered, pharmacy inspectors should be present during the oral conference. As background, EO Sodergren informed the committee that they had over 400 mail votes last year. She also informed the committee, the oral conference itself would have to be publicly agenized but would qualify for closed session.

President Lippe asked DCA Counsel Marks if an amendment could be made today to the proposal to include and oral conference between licensee and the committee. Ms. Marks stated that the Enforcement Committee could include an oral conference, although she would need to do more research about what issues would arise with that. Ms. Marks expressed concern that an oral conference may end up being a “mini-hearing” and issues may arise with what is admissible. Counsel Marks clarified that an oral conference may be included in the proposal, but she advised the committee to clarify under what circumstances an oral conference proceeding is used.

The committee agreed to consider this matter further during a future committee meeting.

7. <u>Discussion and Consideration of Policy Regarding Referrals by Pharmacies and Pharmacists to Law Enforcement for Narcotic Diversion by Employees</u>

Chairperson Schaad provided relevant background. He stated the board routinely investigates and acts against licensees involved with drug diversion in pharmacies. In addition to

establishing requirements (e.g., the inventory reconciliation regulations) and developing training (including the Prescription Drug Abuse Prevention CE training), the board has discussed other measures to prevent drug theft by pharmacy employees.

Chairperson Schaad informed the committee, members have suggested an additional opportunity may include local prosecution of pharmacy employees diverting drugs. He stated members have been advised about efforts to work with law enforcement agencies on joint investigations, some of the challenges the board faces with referring matters to local law enforcement, and as well as the board's inability to act against non-licensed pharmacy personnel.

He stated the board previously decided not to pursue mandating referral of drug diversion cases to local law enforcement agencies. As an alternative to a mandate, the committee and board may wish to consider adopting a policy statement regarding referral of drug diversion cases to local law enforcement.

Chairperson Schaad provided for committee review the following draft policy statement which encourages licensees to contact local law enforcement for guidance on matters involving narcotics diversion by its employees, "*In recognition of the ongoing national opioid crisis and in addition the mandatory reporting obligations to the Board included in BPC 4104, the board encourages pharmacies and pharmacists to contact local law enforcement for guidance on matters involving narcotics diversion by its employees."*

Committee Member Wong stated that he would like to do something more drastic than issuing a policy statement.

Committee Member Serpa recommended licensees could be educated about the policy via an article published in The Script and included during the Prescription Drug Abuse Training.

During public comment Dr. Steve Gray stated that it would be helpful to make more people aware of the policy statement. Personally, he stated he would make students aware in his law classes. Additionally, he suggested replacing the word "narcotics" with "all prescription drugs."

Chairperson Schaad proposed the following policy statement with proposed edits, *"In recognition of the ongoing national opioid crisis and in addition the mandatory reporting obligations to the Board included in BPC 4104, the board encourages pharmacies and pharmacists to report to law enforcement matters involving drug diversion."*

Motion: Recommend to the full board the proposed policy regarding referrals by pharmacies and pharmacists to law enforcement for drug diversion.

M/S: Wong /Lippe
Support:5 Oppose:0 Abstain:0

8. Discussion and Consideration of DEA Suspicious Orders Report System (SORS) and Mandatory Reporting Requirement

Chairperson Schaad provided SORS and Mandatory Reporting Requirements for information only to the committee.

He stated, on October 23, 2019, DEA launched the Suspicious Orders Report System (SORS) Online which is a new centralized database required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115-271). The SUPPORT Act requires that all DEA registrants that distribute controlled substances report suspicious orders to DEA, including pharmacies, wholesalers and clinics.

9. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad provided committee with enforcement statistics for the first two quarters of the fiscal year.

He informed the committee since July 1, 2019, the board received 1,307 complaints and has closed 1,437 investigations. The board has issued 191 Letters of Admonishment, 785 Citations and referred 119 cases to the Office of the Attorney General. The board has secured six interim suspension orders, been granted two Penal Code 23 suspensions, and issued one Cease and Desist order. Further, the board has revoked 59 licenses, accepted the disciplinary surrender of 57 licenses, denied seven applications, and imposed other levels of discipline against 90 licensees and/or applicants.

Chairperson Schaad stated, the board currently has 1,473 field investigations pending, as of January 16, 2020. Below is a breakdown providing more detail in the various investigation process:

- 79 cases under review for assignment, averaging 20 days
- 1,010 cases under investigation, averaging 186 days
- 261 investigations under supervisor review, averaging 107 days
- 46 investigations under second level review, averaging 20 days
- 77 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 23 days

After reviewing the investigation timeframes, the committee expressed concern with the current supervisor review time. The committee was advised that improvement will be reported during the next meeting.

10. Future Committee Meeting Dates

Chairperson Schaad stated that the next committee meeting dates are scheduled for May 6, 2020, July 9, 2020, July 29, 2020 and October 27, 2020.