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

ENFORCEMENT COMMITTEE REPORT
Chair Report

Allen Schaad, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

The Enforcement Committee will meet on January 29, 2020. An update of the work of the committee will be provided during the board meeting.

a. <u>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</u>

Attachment 1

<u>Relevant Law</u>
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.

<u>Background</u>
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 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.

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 requirements for inventory requirements ADDS used in an inpatient hospital as well as clarity on the satellite pharmacy.

<u>For Committee Discussion</u>
Subsequent to the board meeting, and in consideration of comments received by the board and public, the chair worked with staff and counsel to draft possible amendments to the current regulation. As included in the proposal, an electronic signature provision is incorporated. Further, a more targeted approach is being offered for drugs in other schedules. Specifically, as included in

attached proposal, specified medication/strengths would require inventory reconciliation reporting on an annual basis including:

- Alprazolam 1mg
- Alprazolam 2mg
- Tramadol 50mg
- Promethazine/Codeine (6.25mg/10mg)/5ml

Provided below is a list these medications and the approximate number of dosage units reported as missing during the last fiscal year:

Additional Reportable Medications	Approximate Dosage Units Reported in FY 2018/2019
Alprazolam 1mg	36,495
Alprazolam 2mg	96,890
Tramadol 50mg	29,546
Promethazine/Codeine (6.25mg/10mg)/5ml	82,326

During the meeting it may be appropriate for the committee to consider the revised proposal to determine if it addresses the board's concerns.

Attachment 1 includes a copy of the proposed language.

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

Attachment 2

Relevant Law

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 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."

Background

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 in the Federal Code of Regulations (FCR) requirements and California Code of Regulations (CCR). 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.

Over the last several meetings, the committee has considered drug loss information data reports, historical and current summary information is provided below. 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 reflects a significant decrease in the overall dosage units reported lost in the most recent fiscal year.

Fiscal Year Reported	Approximate Dosage Units	Approximate # Drug Loss Reports
FY 12/13	1,151,704	754
FY 13/14[1]	1,524,833	1,367
FY 14/15	1,513,696	2,168
FY 15/16	1,646,380	3,481
FY 16/17	2,130,112	7,170
FY 17/18	3,230,016	8,435
FY 18/19	1,427,092	8,939
Total	**12,623,833**	**32,314**

1 One very large loss (1.6 million dosage units+) of benzodiazepines due to an out-of-state loss-in-transit drug loss was not included due to skewing of the data.

The table below reflects the number of reports received during FY 18/19 categorized by the size of the losses. As indicated in the data, the vast majority of reported losses involve 100 or less dosage units.

Loss Size (in dosage units)	Number of Reports
Losses between 0 - 100	8213
Losses between 100 - 500	466
Losses between 500 - 1000	61
Losses between 1000 - 5000	126
Losses over 5000 - 10000	43
Losses over 10,000	30
Total Losses	**8,939**

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

For Committee Discussion

During the meeting members will have the opportunity to discuss the revised proposal. As reflected in the proposal, additional forms of drugs are included to ensure more clarity is provided to the regulated public, while also ensuring professional judgement can be used for some reporting. Overwhelming capsules and tablets represent the most common dosage form for which a drug loss report is submitted.

Attachment 2 includes a copy of proposed draft amendments.

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

Attachment 3

Relevant Law

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.

Background

During the March 4, 2019 committee meeting CPhA provided the committee with a proposal to modify the board current enforcement process. The board disagreed with the proposal but determined that an alternate disciplinary process should be explored. In response, during the July 10, 2019 committee meeting, members were presented with opportunity to discuss a proposal to establish an alternative disciplinary process; the committee allowed board staff the authority to work with the committee chair on items discussed during the meeting and bring a revised proposal back to the committee. During the July 2019 Board Meeting, members expressed support of the framework developed and noted that additional refinement would be completed by the committee.

For Committee Discussion

Subsequent to the board meeting, the committee chair provided guidance to staff on additional elements consistent with the board's direction. During the meeting, members will have the opportunity to discuss the revised proposal to add Business and Professions Code section 4300.2.

The model reflects the basic framework previously discussed by the committee and board, and also incorporates additional procedural items as well as details the involvement of two board members as discussed by the board.

Provided in **Attachment 3** is 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 regarding the board's initial proposal. Also provided is a copy of Government Code section 11425.10 which establishes the governing procedure by which an agency conducting adjudicative proceedings must follow.

d. Discussion and Consideration of Policy Regarding Referrals by Pharmacies and Pharmacists to Law Enforcement for Narcotic Diversion by Employees

Background

The board routinely investigates and takes action against licensees involved with drug diversion in pharmacies. In addition to establishing requirements (e.g., the inventory reconciliation regulations) and developing trainings (including the Prescription Drug Abuse Prevention CE training), the board has discussed other measures to prevent drug theft by pharmacy employees.

Members have suggested an additional opportunity may include local prosecution of pharmacy employees diverting drugs. Members have been advised about efforts to work with law enforcement agencies on joint investigations and some of the challenges the board faces with referring matters to local law enforcement as well as the board's inability to take action against non-licensed pharmacy personnel.

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 such matters also to local law enforcement of drug diversion cases.

For Committee Discussion and Consideration

For committee review, following is a 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.*

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

Relevant Law

21.U.S.C.832(a)(3) (3) provides that each registrant shall—upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

Background

On October 23, 2019, DEA launched the Suspicious Orders Report System (SORS) Online, 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.

Reporting a suspicious order to SORS Online constitutes compliance with the reporting requirement under 21 U.S.C. 832(a)(3).

Committee Discussion

Staff is providing this item for the board's information. Several of the board's licensee types are impacted by the mandatory reporting requirement including distributor, pharmacy and hospital/clinic licensees.

f. Discussion and Consideration of Board's Enforcement Statistics

Attachment 4

Enforcement statistics are for the first two quarters of FY 2019/20 have been provided as **Attachment 4.**

Since July 1, the board received 1307 complaints and has closed 1437 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. 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.

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

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

The following are the committee dates scheduled for 2020:

- May 6, 2020
- July 9, 2020
- October 27, 2020

Attachment 5 includes Draft minutes from the November 5 Enforcement Committee meeting.

Attachment 1

CCR 1715.65
Proposed Language

§ 1715.65. Inventory Reconciliation Report of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:

(1) For Schedule II controlled substances, at least once every three months.

(2) For products containing controlled substances listed in this paragraph in the following strengths, at least once every 12 months:

(A) Alprazolam, 1 milligram.

(B) Alprazolam 2 milligrams

(C) Tramadol 50 milligrams.

(D) Promethazine/Codeine, 6.25 milligrams/10 milligrams per 5 milliliters of product

(3) For all other controlled substances, on a periodic basis.

(b) The pharmacist-in-charge of a pharmacy or ~~consultant~~ consulting pharmacist for a clinic shall review all inventory performed and inventory reconciliation reports ~~taken~~ prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled ~~drugs~~ substances. Written policies and procedures shall be developed for ~~performing~~ preparing the inventory reconciliation reports required by this section.

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) Possible causes of overages ~~shall be identified in writing and incorporated into the inventory reconciliation report~~.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or

self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances.

(e)(1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-in-charge or professional director (if a clinic) ~~and~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report ~~as required in subdivision (c)~~ for all federal controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare inventory reconciliation reports for all federal controlled substances on a ~~separate~~ quarterly basis, ~~inventory reconciliation report shall be required~~ including separate quarterly reports for federal ~~Schedule II~~ controlled substances stored within the pharmacy ~~and~~, for each pharmacy satellite location, and for each drug storage area within the hospital under the pharmacy's control.

(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~shall ensure that:~~

~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~

~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~

~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~

~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

Attachment 2

Draft Amendments

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.

(3) Any other substantial loss as determined by the pharmacist-in-charge.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions Code.

Attachment 3

Draft Statutory Proposal
Government Code section 11425.10
Letter from CPhA

Proposal to Add Section 4300.2

Notwithstanding the provisions of Government Code section 11415.60(b), the Board may offer, and a licensee may accept, a stipulated agreement to license discipline without and in advance of the filing of an accusation or other agency pleading, under the following conditions:

1. Enforcement staff or investigators for the board conducted an inspection or investigation as provided for in this chapter and substantiated violations of law.
2. Enforcement staff at the board provides the licensee with findings of the violations in writing, and a notice of possible eligibility for a pre-filing settlement.
3. The licensee, within 15 days of being provided with the findings of the violations, notified the board in writing of the licensee's willingness to waive the administrative adjudication provisions of the Administrative Procedure Act, including notice and hearing requirements, and to consider a pre-filing settlement as an alternative to action taken on the basis of a pleading. The board may, for good cause, extend the deadline for the licensee to respond in writing beyond 15 days.
4. In order to be eligible for consideration for a pre-filing settlement, the licensee must submit mitigation and rehabilitation information as specified in the board's Disciplinary Guidelines. A committee consisting of the Executive Officer and two members of the Board, one (1) public member and one (1) licensee member, will consider the mitigation and rehabilitation information and may, in their sole discretion, extend a pre-filing settlement offer to the licensee. Any settlement offer shall be based on the violations substantiated by the investigation, and shall be consistent with the board's Disciplinary Guidelines. Nothing in this section should be construed to limit or prohibit any and all good faith settlement negotiations.
5. The proposed settlement agreement in the form of a Stipulated Settlement and Disciplinary Order, and incorporating the findings of the violations, must be agreed to in writing within sixty (60) calendar days of the date of the licensee's waiver. The committee may agree to extend this time period at their exclusive discretion. Any such extension must be in writing, and shall be granted only for good cause or when good faith settlement discussions are ongoing.
6. If the parties have failed to come to agreement within the time limits set forth in paragraph 5, the board shall proceed to file the appropriate disciplinary pleading.
7. The Stipulated Settlement and Disciplinary Order is contingent upon approval by the board itself, except that the members of the committee shall recuse themselves and not participate or vote on the Stipulated Settlement and Disciplinary Order.
8. If the Stipulated Settlement and Disciplinary Order is adopted by the board itself, it shall be a public document in accordance with Business and Professions Code section 27 and the California Public Records Act.
9. If the board itself fails to adopt the Stipulated Settlement and Disciplinary Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, and the board itself shall not be disqualified from further action by having offered or considered the Stipulated Settlement and Disciplinary Order.
10. If the board itself fails to adopt the Stipulated Settlement and Disciplinary Order, the board will file the appropriate disciplinary pleading. Nothing in this section should be construed to limit the ability of the parties to negotiate and enter into a Stipulated Settlement and Disciplinary Order after the disciplinary pleading has been filed.

State of California

GOVERNMENT CODE

Section 11425.10

11425.10. (a) The governing procedure by which an agency conducts an adjudicative proceeding is subject to all of the following requirements:

(1) The agency shall give the person to which the agency action is directed notice and an opportunity to be heard, including the opportunity to present and rebut evidence.

(2) The agency shall make available to the person to which the agency action is directed a copy of the governing procedure, including a statement whether Chapter 5 (commencing with Section 11500) is applicable to the proceeding.

(3) The hearing shall be open to public observation as provided in Section 11425.20.

(4) The adjudicative function shall be separated from the investigative, prosecutorial, and advocacy functions within the agency as provided in Section 11425.30.

(5) The presiding officer is subject to disqualification for bias, prejudice, or interest as provided in Section 11425.40.

(6) The decision shall be in writing, be based on the record, and include a statement of the factual and legal basis of the decision as provided in Section 11425.50.

(7) A decision may not be relied on as precedent unless the agency designates and indexes the decision as precedent as provided in Section 11425.60.

(8) Ex parte communications shall be restricted as provided in Article 7 (commencing with Section 11430.10).

(9) Language assistance shall be made available as provided in Article 8 (commencing with Section 11435.05) by an agency described in Section 11018 or 11435.15.

(b) The requirements of this section apply to the governing procedure by which an agency conducts an adjudicative proceeding without further action by the agency, and prevail over a conflicting or inconsistent provision of the governing procedure, subject to Section 11415.20. The governing procedure by which an agency conducts an adjudicative proceeding may include provisions equivalent to, or more protective of the rights of the person to which the agency action is directed than, the requirements of this section.

(Added by Stats. 1995, Ch. 938, Sec. 21. Effective January 1, 1996. Operative July 1, 1997, by Sec. 98 of Ch. 938 and Section 11400.10.)

california **pharmacists** association

July 17, 2019

Victor Law, R.Ph
President, California Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Dear President Law,

On behalf of the California Pharmacists Association (CPhA), I would like to submit some comments addressing the topic of the 'alternate disciplinary process' which will be considered at the Board Meeting on July 24 and 25 in Anaheim, CA.

First, CPhA would like to thank you and Enforcement Committee Chair Allen Schaad for the Board's work on addressing the creation of an alternate disciplinary process for licensees with matters being referred to the Attorney General's office for prosecution. The alternate plan that was offered during the July 10 Enforcement Committee, and being considered for adoption by the full board, is a great step in the right direction. Our members appreciate the potential opportunity to address an alleged serious disciplinary issue in a way that allows for board member involvement before going through the onerous process of the legal system. CPhA believes that this option will not only speed up disciplinary cases, but will also save the licensee and the Board time and money and provide a fairer occasion to provide mitigating evidence, if applicable. Many other states, including Arizona, Texas, Florida, Maryland, Washington and others, provide for their board members to be involved in the disciplinary process. This has statistically led to fewer cases being heard by an administrative law judge (ALJ), and quicker resolutions.

While we appreciate that California's Board seems to be moving in that direction, we'd like to offer some suggested changes to the Board's proposal that will help further get to the Board's goal of being less punitive and more collaborative and education-driven with its licensees.

Proposal to Add Section 4300.2 (red is CPhA's proposed additions and blue is CPhA's proposed strikeouts)

Notwithstanding the provisions of Government Code section 11415.60, the Executive Officer may offer, and a licensee may accept, a stipulated agreement to license discipline without and in advance of the filing of an accusation or other agency pleading, under the following conditions:

1. The board conducted an inspection or investigation as provided for in this chapter and ~~substantiated~~ alleges violations of law that warrant disciplinary action.

2. The board advised the licensee of the ~~substantiated~~ alleged violations in writing.

3. The licensee, within 15 days of being advised of the violations, notified the board in writing of his or her willingness to conditionally waive the administrative adjudication provisions of the Administrative Procedure Act, including notice and hearing requirements, ~~and to~~ for purposes of considering a pre-filing settlement as an alternative to action taken on the basis of a pleading. The Executive Officer retains discretionary authority to extend the deadline to respond in writing beyond 15 days.

> *(i) The licensee may submit mitigation evidence to the Executive Officer for their consideration.*

4. ~~The~~ If an agreed settlement ~~is based on the violations alleged or found~~ includes~~, and~~ any discipline ~~proposed is~~ by the Board arising from violations that are substantiated, that discipline shall be consistent with the board's Disciplinary Guidelines.

If no pre-filing settlement between the Executive Officer and the licensee is agreed to in writing and in good faith by both parties, within 60 days of the licensee's notification of waiver, the Executive Officer may proceed to direct the Attorney General's Office to prepare the appropriate pleading.

Any pre-filing settlement agreement reached between the Executive Officer and a licensee is contingent on approval by the board ~~itself~~. The board ~~itself~~ retains full authority and discretion to adopt, request modification to, or reject any such agreement. If the board requests modification to an agreement ~~is rejected by the board itself~~, the Executive Officer may offer a revised pre-filing settlement agreement consistent with any guidance from the board. ~~itself~~ If the board rejects the agreement, the Executive Officer ~~or~~ may proceed to direct the Attorney General's Office to prepare the appropriate pleading.

We believe these changes accomplish several goals. The first goal is to clarify that unless and until a licensee has agreed to a stipulated agreement resulting in disciplinary action from the Board, or had official disciplinary action taken against them resulting from an ALJ, the licensee is only alleged to have violated the law. CPhA would not want to bias the new alternate disciplinary process by assuming a violation has occurred.

Second, CPhA would not support the waiving of any rights afforded to licensees simply because they chose this alternate route. CPhA believes that it's appropriate to waive these rights, as a condition of expediting the process of this alternate disciplinary route. However, if the licensee is unable to obtain an approved settlement, they should still be able to retain their rights under the Administrative Procedures Act when going through the traditional disciplinary process.

Third, CPhA would like to include in the statutory proposal that the licensee may submit mitigating evidence as outlined in the meeting materials of the July 10 Enforcement Committee meeting.

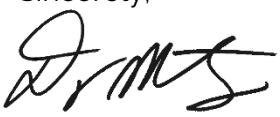
Fourth, CPhA would like to clarify that any settlement which results in disciplinary action by the Board will be consistent with the Board's Disciplinary Guidelines. This allows any settlement which may result in non-disciplinary action (e.g. a cite/fine, letter of admonishment, etc) to not have to be subject to the Disciplinary Guidelines.

Lastly, CPhA agrees that the Board should retain full authority to accept or reject a settlement that is presented. However, it should also have the authority to request modifications to the agreement if the Board deems necessary to do so. The current proposal only gives the Board the option to accept or reject and subsequently the Executive Officer to refer to the Attorney General. CPhA's suggested changes allow the Board to request a modification to the agreement if necessary, maintaining their involvement in the disciplinary process.

Again, CPhA is pleased to see the direction this proposal is going towards and we thank the Board and its staff for the work done on this. Should you have any questions about these suggested changes, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com. I will also be at the Board's meeting in Anaheim to address questions or concerns in person.

Thank you for your consideration of our comments.

Sincerely,



Danny Martinez
Government Relations and External Affairs Manager
California Pharmacists Association.

Attachment 4

Enforcement Statistics
A hard copy will be made available at the meeting or upon request. Requests may be emailed to MaryJo Tobola at MaryJo.Tobola@dca.ca.gov

Attachment 5

Draft Enforcement Committee

Minutes November 5, 2019

California State Board of Pharmacy
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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.