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

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE: July 10, 2019

LOCATION: Department of Consumer Affairs - Building Two
1747 North Market Blvd., Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Allen Schaad, Licensee Member, 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
Joshua Room, Supervising Deputy Attorney General
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 9:01 a.m. A quorum was established.

2. Public Comment on Items Not on the Agenda, Matters for Future Meetings

Chairperson Schaad invited public comment.

Dr. Steven Gray suggested that Senate Bill 1442 be considered as a future agenda item. Interim Executive Officer Anne Sodergren stated that the discussion of SB 1442 is on the agenda for the July 2019 Legislation and Regulation Committee meeting. Dr. Gray responded, his request is to have SB 1442 placed specifically on the Enforcement Committee meeting agenda, in order to discuss the actual enforcement of SB 1442.

Robert Stein of KGI School of Pharmacy stated that he would provide suggested edits for the draft version of the Self-Assessment for Community Pharmacies form. Mr. Stein stated that those suggested edits would be forwarded to Ms. Sodergren for consideration.

3. **Approval of the March 14, 2019 Enforcement Committee Minutes**

Chairperson Schaad requested the review and approval of the Minutes from the March 14, 2019 Enforcement Committee meeting.

Motion: Approve the minutes, as is.

M/S: Lippe/Sanchez

Support: 4 Oppose: 0 Abstain: 0

4. **Presentation and Discussion on the Board's Citation and Fine Program**

Chairperson Schaad provided relevant law. Business and Professions Code section 4314 established the authority for the board to issue citations, which may include fines and/or orders of abatement. As included in this section, the order of abatement (OOA) may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.

Additionally, Title 16, California Code of Regulations (CCR) sections 1775-1775.4, provide the board's regulations governing its citation and fine program. More specifically, section 1775 details the types of violation for which a citation may be issued and includes the authority of the executive officer or designee to issue citations, which may contain either or both an administrative fine and an order of abatement.

Section 1775.2 establishes the factors to be considered in assessing an administrative fine. Such factors include:

1. The gravity of the violation.
2. The good or bad faith of the cited person or entity.
3. The history of previous violations.
4. Evidence that the violation was or was not willful.
5. The extent to which the cited person or entity has cooperated with the board's investigation.
6. The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violations.
7. Other matters as may be appropriate.
8. The number of violations found in the investigation.

Further, section 1775.3 establishes the OOA compliance requirements.

Chairperson Schaad provided background information. For several meetings the committee has discussed several aspects of the board's citation and fine program. Chairperson Schaad reminded the committee that during the May 2018 Board meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved medication errors. He stated that the committee continues the review of the citation and fine program.

Members received a presentation on citation and fine trends from Anne Sodergren. Data was presented covering Fiscal Years from 2014 to 2019, regarding citations issued, Orders of Abatement issued, top citation violations and citation examples in the area of medication errors and prescription disclosure errors.

Chairperson Schaad suggested that this presentation along with examples of abatements be published in The Script newsletter.

The committee heard public comments which requested clarification on the OOA issuance process and whether an OOA must always be associated with a citation. In response, SDAG Room clarified that an OOA is issued with a citation and the OOA must be complied with in order to satisfy the citation, otherwise, disciplinary action may result. Additionally, Ms. Sodergren clarified that in some circumstances, when an OOA is completed the fine may be reduced.

Further, the committee was asked who is expected to sign an OOA. Member Lippe responded that signature may depend on who the citation is issued against.

As part of additional public comment, the committee was asked if there are specific criteria that must be met for a licensee to correct a violation by an OOA. In response, SDAG Room stated that there are no guidelines for issuance of an OOA. When the committee was asked if a licensee could request an OOA rather than a citation, Ms. Sodergren clarified that licensees do not have the option to select an OOA; an OOA is a condition of the issuance of the citation. When asked what recourse a licensee has when they feel that a violation could be better resolved with an OOA rather than just a citation, SDAG Room stated that a licensee may request an Office Conference; every citation issued is subject to modification or dismissal at the Office Conference.

5. **Post Implementation Review of Inventory Reconciliation Requirements for Controlled Substances, Including Discussion and Consideration of Title 16, California Code of Regulations Section 1715.65**

Chairperson Schaad provided background and relevant law. In April 2018, Title 16, CCR 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. Chairperson Schaad informed the committee that since that time the board has provided guidance documents including FAQs that are published on the board's website. He stated that board staff continue to receive questions regarding the regulation requirements.

Chairperson Schaad provided a sample of the types of questions in the Chair Report for review.

Chairperson Schaad stated that in addition, considering the recent enactment of the Automated Drug Delivery Systems (ADDS) provisions, it seemed appropriate to complete a post implementation review of the regulation to determine if additional guidance or changes may be necessary to meet the board's policy goal of the regulation.

Ms. Sodergren suggested that the committee may want to consider policy direction with respect to drugs in the ADDS devices as well and discuss more clear directions for devices in hospital settings and satellite locations.

As part of public comment, Mr. Martinez of CPhA requested clarification on how bulk powder substances should be reconciled on the Inventory Reconciliation Report. Chairperson Schaad advised that powdered substances should be weighed.

As part of public comment, Candace Fong of Dignity Health informed the committee that with respect to reconciliation of Schedule II Controlled Substances (CIIs), the ADDS devices located in their hospitals are already subject to internal processes, which are on a perpetual closed-loop inventory. In their opinion, to physically have to count the CIIs on a quarterly basis, given their

internal controls, is repetitive and not considered a wise use of their resources. Many Dignity Health hospitals have up to 75 ADDS machines. Their understanding, when the regulations were released, was that hospitals would be required to establish policies and procedures to support an inventory process to monitor controlled substances in the ADDS, which would remove hospitals from the physical inventory requirement. Dr. Fong also stated that when the FAQs were released and inspections commenced, there was confusion on the implementation of inventory reconciliation of ADDS in hospital settings. She stated that Dignity Health is in support of limiting the physical inventory requirement to the pharmacy's central vault area and not include the devices.

As part of public comment, Mr. Stein of KGI School of Pharmacy stated, in his own professional experience, hospitals have strict controls over dispensing devices. He stated the regulation implies that a pharmacist must conduct the inventory counting; however, if there are controls already in place that adequately ensure that an accurate inventory is conducted by nurses, even more frequently than required by the regulation, such a process should already be compliant with the law.

Chairperson Schaad recommended there should be clarification provided regarding inventory reconciliation of ADDS in satellite locations, as well as guidance on inventory requirements in hospital settings. Chairperson Schaad stated, ADDS located in hospital settings are subject to strict checks and balances, which already ensure the protection of the public and as a result, the degree of drug loss is less. Chairperson Schaad stated he would like to ensure hospitals are not put in a position to unnecessarily have to spend time completing an inventory that will have very little value.

Ms. Sodergren suggested that the committee may want to consider a policy discussion on satellite location requirements, based on their individual location. For example, the requirements of an ADDS located in a hospital may differ from the requirements of an ADDS located in a skilled nursing facility.

DCA Staff Counsel Laura Freedman suggested it may be appropriate to provide clarification about who may sign the Inventory Reconciliation Report.

As part of the public comment, a CVS Health Representative opined that the inventory reconciliation requirements are written from an antiquated perspective in that many pharmacy systems have the electronic capabilities to document every pharmacist involved in the distribution of CIIs. He stated the current requirement for a signature and date causes each pharmacist who may have performed a single count of medication to be tracked down which is not always logistically possible. He asked that board inspectors either use discretion in the enforcement of this regulation and consider the established electronic documentation already in place or the board amend the regulation to consider electronic documentation in lieu of actual signatures.

As part of the public comment, a representative from Albertson's requested that the committee clarify or define the term "periodic" regarding the periodic inventory requirement.

As part of public comment, Dr. Gray requested clarification on the retention requirement of three years for inventory reconciliation reports. Specifically, he asked if an electronic inventory record, which staff has access to in the pharmacy, meets the retention requirement. Board Member Lippe confirmed that the regulation states that the reports should be in a "readily retrievable form" which

would include an electronic copy of the report. Additionally, Dr. Gray had comments on FAQs; Ms. Sodergren requested that Dr. Gray submit those comments to the board.

The committee took a break at 10:07a.m. and returned at 10:27 a.m.

Chairperson Schaad summarized that pursuant to committee discussion of Section 1715.65, board staff will work with the committee chair to discuss and develop recommendations for the following topics of concern:

- Specify requirements of ADDS in hospitals,
- Define a satellite pharmacy,
- Review FAQ pursuant to recommendations submitted during public comment,
- Discuss the use of electronic documentation of reconciliation, and
- Define periodic.

6. <u>Discussion and Consideration of Reporting Drug Losses to the Board Pursuant to Title 16, California Code of Regulations, Section 1715.6</u>

Chairperson Schaad provided background and 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."

Mr. Schaad stated that as part of past board discussions related to the board's new inventory reconciliation regulation, the issue of drug loss reporting requirements was mentioned. It was brought to the board's attention the difference in the Code of Federal Regulations (CFR) requirements and California Code of Regulations (CCR). During the rulemaking process, it was suggested that the board amend its current drug loss requirement (CCR 1715.6) to mirror the DEA requirements. At that time, committee 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 informed the committee the Chair Report included summary data regarding drug losses. Also, Attachment 3 provided additional information regarding the types of losses that fall within the 1-100 dosage unit range.

Chairperson Schaad recommended a correction of the Morphine data provided in Attachment 3.

Ms. Sodergren stated that there have been numerous discussions on whether there is value in receiving reports of every loss, as the law currently requires. The question arises, should the committee establish a different threshold? Ms. Sodergren suggested the committee discuss whether they agree with what the regulation currently requires. If the committee determines there is little value added to consumer protection with the notification of every pill loss, it may be appropriate for staff to work offline with the committee Chair, based on the data provided, to determine if a new reporting requirement should be considered.

In response, Chairperson Schaad stated that the current reporting requirements are confusing and reporting criteria should be more manageable. Chairperson Schaad informed that committee that he will work with board staff in the development of new reporting thresholds.

The committee heard public comment which encouraged the committee to not require the report of every schedule, every type of drug or number of dosage units lost. The board was encouraged to adopt a regulation that states that pharmacists, pharmacies, etc. shall follow the reporting requirement of the Drug Enforcement Administration (DEA) and any report that is made to the DEA also must be made to the board. He stated that there is opportunity now, by statute or by regulation, to have pharmacists, PICs and consulting pharmacists adopt their own policies and procedures using their professional judgement in conjunction with the six criteria identified by the DEA to determine what ought to be reported

7. <u>Discussion on and Consideration of Proposal to Establish an Alternative Disciplinary Process</u>

Chairperson Schaad provided background and 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.

He stated that previously the committee received a presentation by the California Pharmacists Association (CPhA), seeking to establish an alternative enforcement model. The committee expressed concerns with the proposal but directed staff to develop a possible alternative enforcement model that would meet two primary goals - - reduce cost and reduce closure times. Consistent with the direction of the committee, staff worked with the committee chair on the basic framework for an alternative model.

Chairperson Schaad invited board staff to provide a brief summary of the proposal.

Ms. Sodergren provided a review of the flowchart depicting the proposed concept of an alternative disciplinary process. Ms. Sodergren detailed that the flowchart was designed with consideration to the feedback that was shared at the last committee meeting.

Ms. Sodergren provided a description of the alternative model:

1. Investigation is completed and violations are substantiated that warrant referral to the Office of the Attorney General (AG's Office) for disciplinary charges.
2. Respondent is advised of the violations and the board's intentions to refer the matter to the AG's Office for disciplinary charges. As part of the advisement, respondent is provided the option to pursue the alternate model.
3. Matter is referred to the AG's Office.
4. Board receives respondent's notice electing to engage in the alternate model. Respondent may also provide any mitigation evidence.
5. Executive Officer (EO) and 2 board members (one public member and one licensee member) review investigation and mitigation, if any.
6. Settlement offer is developed and conveyed by AG's Office to respondent.
7. Upon agreement, the settlement along with the initial notice to respondent advising of the

substantiated violations are considered by the board for action.

In addition, Ms. Sodergren presented the draft statutory proposal intended to detail the basic tenets of the proposal. She explained that in its current form, the language is a concept and not yet ready for sponsorship. If the committee is in in agreement with the direction and concept of this as an alternative solution, this could be brought before the full board to request approval for board staff to continue the development of the statutory proposal with the committee chair.

As part of the public discussion, Danny Martinez of CPhA asked if the referral to the Office of the Attorney General be prevented or avoided in this alternative model in order to expedite the process? SDAG Room clarified that cases are routinely referred to the Office of the Attorney General to prepare the pleadings. Referrals, for these types of cases would be for purposes of pre-filing settlement; the Office of the AG has the standard templates used for stipulations, provides the reviewing the mitigation and packaging it for purposes of the board. SDAG stated that at this point, an Accusation is not being prepared.

Mr. Martinez also asked, under review of the investigation by the EO & two board members, would the committee consider increasing that panel to 3 board members, specifically 2 licensees and one public board member? Acting President Lippe responded, adding more professional than public members is in direct opposition to the concept behind having public members. He emphasized, three board members would place control in the hands of licensees, while the goal is to equal control of decisions.

In addition, Mr. Martinez asked, if a licensee chooses to use the alternative route, will the licensee have an opportunity to prove their innocence? SDAG Room clarified that the alternative route is to be used for cases where investigations have already been completed and the violations that would warrant discipline have already been substantiated. These are cases where the executive officer has already determined that the case would be referred to the Office of the AG and this is an alternative to the immediate referral for pleading. The licensee has already been provided the opportunity to provide information to dispute the violation during the investigation.

Mr. Martinez asked if it is possible for the licensee to provide evidence before the panel to prove that he/she committed no violation? Ms. Sodergren responded, if there is supplemental information to be considered that will be included as part of the mitigation. DCA Counsel Freedman stated that this process would not prohibit the EO from recommending that a pleading should not be drafted.

Mr. Martinez also asked if the licensee responds within the 60-day period, but a settlement is not agreed upon within the 60 days, may an extension be granted? SDAG Room and Ms. Sodergren confirmed that the 60-day period is for agreement to settlement; at that time the EO may forward the case to the AG's Office to prepare the pleading or grant additional time.

Mr. Martinez stated that CPhA would prepare additional comments for board for consideration while board staff finalize this proposal.

Ms. Sodergren reminded the public, at this point, staff is discussing high-level basic concepts, the proposal will need to be further refinement while considering existing policy and statute. Currently neither the committee nor the board can answer some of the very detailed questions.

As part of public discussion, various members of the public contributed suggestions to be considered as the proposal is refined. Some of the suggestions included: The Executive Officer should present the information to the panel, but not be allowed to vote; a third board member should be included in the panel who has actual pharmacy experience instead of the executive officer; the panel should consist of 3 to 5 board members. Suggested language was provided to the board for review.

A member of the public suggested that the licensed board member assigned to the panel be selected for each case according to their area of practice. SDAG Room responded that the board is designed to operate by the majority vote of public and licensee members; they are not required to bring any particular expertise to the board. Board members are required to rely on the investigation reports. He advised against creating any circumstance by which certain board members would be designated for certain types of cases and not others.

SDAG Room cautioned the board against any circumstance where public members' votes would be automatically outweighed by licensed members' votes due to the potential for liability under the North Carolina Dental Board Case.

Motion: Take the proposal to establish an alternative disciplinary model to the full board.
M/S: Lippe/Wong
Support: 4 Oppose: 0 Abstain: 0

8. <u>Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask an Inspector Program</u>

Chairperson Schaad recommended that this item be brought back to the Enforcement Committee after further review by board staff and the Chair.

Chairperson Schaad invited the public to submit written comments for review and consideration.

9. <u>Discussion and Consideration of Posting of an Individual Licensee's Address of Record on the Board's Website</u>

Chairperson Schaad provided background and relevant law. Government Code Section 6250, et seq, provides that the address of record of board licensees is public information. CCR Section 1727.1 provides that the board shall not make an intern pharmacist's address publicly available on the internet. Beginning in December 2003, the board began posting the Address of Record for board licensees on its website. At that time, it was noted that similar information is provided online by other health profession regulatory boards (physicians, dentists, therapists.) The board noted that because the addresses of record are public record by law, those licensees who wish to withhold their residence address from the public may provide a post office box, a personal mailbox number, place of employment, etc. as the address of record as long as a resident address (which is not available to the public) is also provided.

Chairperson Schaad stated, since that time the board has periodically reminded licensees in newsletters, application forms, etc. that the address of record is posted online, as well as the method by which to change the address of record.

As part of the public discussion, Dr. Steve Gray, representing California Society of Health-System Pharmacists (CSHP), stated that from a safety and protection point of view, it would be best to stop the posting of individual licensee addresses on the board's website. He asked for consideration of a process which better protects the licensees.

DCA Staff Counsel Laura Freedman stated, when a license is granted, the Public Records Act (PRA) and the Information Practice Act say the right to have a license comes with requirements established for consumer protection. By providing an address, a consumer who is trying to determine whether an individual is a qualified practitioner can go to that regulatory agency and determine whether the individual has the skills and license. The benefit of providing an address is if the licensee has a common name, it helps the consumer narrow down which licensee they are researching by knowing their location of practice.

Chairperson Schaad shared his concern, unlike most licensed professions pharmacists have access to items of value and are vulnerable to theft; by providing their address it may comprise their personal safety. DCA Counsel Freedman responded, other offices, such as the Bureau of Cannabis Control, whose licensees also have access to items of value, are required by statute to provide an address of record.

Ms. Sodergren clarified, it is her understanding that the PRA specifies the address of record of a licensee is public information. She confirmed that there are programs within DCA that are statutorily mandated to post. She stated she does not believe that Board of Pharmacy is included in that list of those mandated.

Ms. Sodergren informed the committee, it would require statutory change to the Government Code to make the address of record private. She added, the administration historically has been in support of putting the address of record on the website, therefore, in 2003 the board started to post addresses of record on the board website. Ms. Sodergren stated, board staff can look at changing the current practice and discuss with the administration to see whether it is appropriate. She informed the committee, boards comply with this law differently, compliance may be based on the functions of the computer systems they have.

Ms. Sodergren stated, the committee should decide from the policy standpoint if the policy to post the address on the website should be changed and then give staff the opportunity to come back to the committee with information as to whether the technology supports the change. If the committee decides to pursue changing the policy, she requested that the committee give staff the opportunity to talk to others that may have an opinion on this subject and determine if there is a balance that can be met.

Ms. Sodergren clarified, even if licensee addresses are removed from the website, by law, addresses are still public information, therefore, the board is still required to release that information, upon request. She also informed the committee, there is a provision in the law that states if there is a protective order issued by the court the board is not required to release information.

Chairperson Schaad recommended to move forward into revising the board policy since the website posting of addresses presents a particular danger to board licensees. Ms. Sodergren stated that she would work with the board chair on the revision.

10. Presentation on Board's Jurisdiction in Enforcement Matters Regarding Pharmacies Operating Under Common Ownership or Management

Chairperson Schaad introduced Supervising Deputy Attorney General Joshua Room who provided a presentation on the board's jurisdiction in enforcement matters regarding pharmacies operating under common ownership or management.

SDAG Room stated that there are many advantages and reasons that each site is licensed and regulated individually; it makes each site responsible for its own conduct. However, he stated, there are many instances of corporate policies, that are not set at a store level that may lead to disciplinary action where remediating that policy at an individual store level may seem either unfair or inadequate. As an example, staffing requirement decisions are not usually made at the store level for chain pharmacies, but rather at the executive or corporate HR level; therefore, when there are staffing violations due to their own staffing policy, each pharmacy within the chain would be cited. As another example, when a corporate system fails to adequately vet their employees in order to determine what their current license status is, should each pharmacy in which that individual subsequently works be cited and subject to discipline or should there be a larger sanction for the whole corporate entity since it was a failure of their human resources department. SDAG Room also provided an example from several years ago, when in response to many store level violations regarding patient consultations, the board was able to work in cooperation with some DA offices to secure larger penalties against the chains. He explained, this is not something that can be relied up on as a consistent enforcement mechanism. SDAG Room stated, these are examples of system-wide policies where individual sites sanctions may not address the issue.

SDAG Room explained, currently, unless the board wants to cite each pharmacy in violation individually, it is difficult to address these types of violations in a large-scale way. There have been instances where the board has written into an individual licensee stipulation that the chain has to make a correction; this is an indirect way of addressing an issue. SDAG Room summarized that this is a deficit in the enforcement model we currently have. It may be inadequate to sanction an individual site for a system-wide problem because it is either unfair on inadequate or may fail to encourage system-wide remediation and the sanction against an individual pharmacy may be inadequate to encourage that chain to take a larger action.

SDAG Room offered possible solutions:

- Issue a master license to the chain or corporate entity that sits above an individual pharmacy licenses. He stated that this solution may be problematic, in that it offers limited options in what sanctions could be taken against such a master license. For instance, if the board wanted to revoke or put the master license on probation it would be less meaningful unless it also has cascading effects on all or some of its sub-licensees.
- Put into law that when some threshold is met when addressing system-wide deficiencies, the owner or operator of that system is made legally accountable for those system-wide deficiencies and legally accountable for system-wide remediation. Similarly, if some form of remediation is ordered against some threshold number of pharmacies in a system-wide pharmacy system then all the pharmacies in that system would be subject to the same requirements and remediation.

SDAG Room explained that the board is experiencing consistent and more frequent issues with system wide deficiencies or with local pharmacies saying they do not have the authority to address system-wide issues identified by inspectors. It appears the board needs some ability to confront the system more directly than by way of its individual licensees.

SDAG Room explained, some ownership structures are very complicated, and most pharmacy entities have multiple layers of ownership. He presented the following challenges for the committee to consider: What level of ownership should be held accountable? If the ownership of the chain is not in CA, what are the jurisdictional issues? Where a potential site or sites is being investigated, what effect on that pending action should a potential sale of the pharmacy have? Should the sale of a pharmacy be subject to the existing disciplinary action? Should the licensee be allowed to sell the pharmacy out of a disciplinary action?

SDAG Room recommended that the committee agendize an item to discuss the possible statutory approaches to addressing multi-pharmacy owners. SDAG Room informed the committee that his recommended options would be a master license, where owners and operators are automatically responsible for occurrences in any of their stores, or remediation ordered at any of their stores must be enforced at all their stores.

Ms. Sodergren suggested that this could be a challenge identified during the Sunset Report process. By doing this the board could provide the legislature with an opportunity to look at the issue as well and come up with possible solutions through the Sunset Report process. Ms. Sodergren suggested that perhaps the committee may also want to look at the fine provisions or the ability to levy larger fines which might provide motivation to make the systemic changes necessary or allow for more control at the store level by PICs. SDAG Room added that is difficult to enforce citation and fines against non-licensed entities.

Chairperson Schaad supported the strategy to include this challenge in the Sunset Report. He stated doing so would allow the board adequate time to work through this issue, while also informing and working with the legislature.

Ms. Sodergren confirmed that that board staff will work on policy background challenges, to frame the discussion, and highlight those challenges as part of the report. Additionally, Chairperson Schaad recommended that staff work with the president and vice president to develop possible solutions to bring back to the full board.

As part to of the public discussion, Dr. Gray of CSHP asked the committee take into consideration the organizational differences of hospitals in the development of the recommendations.

Motion: Board staff will work with the president and vice president on a paper for inclusion in the Sunset Report and the recommended solutions will be developed by the Organizational Development Committee.

M/S: Lippe/Sanchez

Support: 4 Oppose: 0 Abstain: 0

The committee took a lunch break at 12:12 p.m. and returned at 12:36 p.m.

11. Discussion and Consideration of Citations as Non-Disciplinary Actions and Proposal to Amend Business and Professions Code, Section 4314 to include Provisions to that Effect

Chairperson Schaad provided relevant law and background information. He stated Business and Professions Code (BPC) section 4314 established the general statutory authority for the board to issue citations containing fines and orders of abatement for specified violations of law. He informed the committee that the board routinely advises requesting parties that citations issued by the board do not constitute discipline. Rather, a citation is an administrative action taken by the board. Regrettably, there are times when regulators from other jurisdictions may apply a different meaning to the citation.

Chairperson Schaad stated that under the letter of admonishment provisions in BPC section 4315, a provision is included in the statute that explicitly states that a letter of admonishment shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure. No similar provision exists in the board's citation statute.

Chairperson Schaad stated that It may be appropriate for the committee to consider if an amendment to BPC section 4314 is appropriate to establish similar clarification on application of a citation issued by the board.

He informed the committee that the meeting materials included the proposed language and if the committee agrees with the policy proposal, BPC section 4314 could be amended to add the following language:

> (e) The issuance of a citation pursuant to subdivision (a) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

As part of the public discussion, CPhA stated their support of amending BPC section 4314. It was asked if this proposed statutory amendment would change reporting requirements under other boards or agencies within California. Ms. Freedman responded that this amendment would only mandate DCA boards to comply; other boards and agencies outside of DCA would not be subject to the provisions of the statute.

Motion: Recommend sponsoring a statutory change to amend BPC section 4314 as included in the meeting materials to the board.
M/S: Sanchez/Lippe
Support: 4 Oppose: 0 Abstain: 0

12. Discussion and Consideration of Committee's Strategic Goals

Chairperson Schaad stated that in 2016 the board finalized its current strategic plan. He recommended that the committee discuss the status of its strategic goals for the coming fiscal year as well as the remainder of the plan.

Chairperson Schaad reviewed each goal and provided a brief status.

2.1 Implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.
Chairperson Schaad stated that during the March 2019 committee meeting a review of FY 18/19 data reported a significant decrease in the number of pending investigations over 1 year and an improvement in overall investigation times for cases that are closed.

There was no public comment received regarding Strategic Goal 2.1.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.
Chairperson Schaad stated that inspectors continue to include in their routine inspections the pharmacy staff's compliance with consultation laws.

The committee directed staff to provide to the committee data reflecting the total number of routine inspections and of those which identified patient consultation as a violation.

There was no public comment received regarding Strategic Goal 2.2.

2.3 Collect data and report to board members about enforcement trends that are presented at case closures, so the board can better educate licensees about board priorities.
Status:
Chairperson Schaad stated that multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the common violations resulting in the issuance of citations.

There was no public comment received regarding Strategic Goal 2.3

2.4 Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.
Chairperson Schaad stated that the board convened a technology summit on the use of automated drug delivery systems (ADDS) and evaluated the findings of a pilot project to expanding the use of ADDS. The board secured statutory changes to expand the use of ADDS in Senate Bill 1447 (Hernandez, Chapter 666, Statutes of 2018).

As part of public discussion, it was suggested that the committee takes into consideration whether new technologies protect the privacy of patient information.

2.5 Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.
Chairperson Schaad stated that in coordination with the Office of the Attorney General, the board initiated a process to improve the efficiency of the disciplinary process. The overall goal with the cooperation of the Attorney General's Office is to process all cases through the office of the Attorney General within one year. In July 2019, the committee considered an alternative enforcement model.

There was no public comment received regarding Strategic Goal 2.5.

2.6 Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.
Chairperson Schaad informed the committee that no work has been done on this strategic goal. It was decided that the committee would recommend to the board the removal of this as a strategic goal.

There was no public comment received regarding Strategic Goal 2.6.

2.7 Investigate options on the interoperability with a National Prescription Drug Monitoring Program.
Chairperson Schaad stated that Assembly Bill 1751 (Low, Chapter 478, Statutes of 2018) established the authority for the Department of Justice to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information. Ms. Sodergren informed the committee that the Department of Justice has already implemented these provisions.

2.8 Develop a process to submit complaints about inspectors anonymously and report back to the board.
Chairperson Schaad stated that the board has developed a brochure to be distributed to licensees at the time of inspection. Included in the brochure is information on filing a comment or complaint with the board's parent agency, the Department of Consumer Affairs. The brochure is currently under review with the DCA's Legal Department.

In response to public discussion, Ms. Sodergren stated that the brochure has been forwarded to the Communication and Public Education Committee for review and approval.

The committee asked staff to collect data on the number of complaints submitted in the next 6 months.

2.9 Assess the collateral consequences of post discipline and research options.
Chairperson Schaad stated that the enforcement committee has initiated a review of the board's Disciplinary Guidelines.

Chairperson Schaad reported that this is on-going, and the review of guidelines will be addressed at future committee meetings.

There was no public comment received regarding Strategic Goal 2.9.

2.10 Evaluation of the board's Citation and Fine program.
Chairperson Schaad stated that the committee has received several presentations on the citation and fine program and will continue to receive annual updates. At the policy direction of the board, staff is availing itself of the Order of Abatement authority at a much higher rate. Further, under the direction of the president and vice president, policy direction on other factors that should be considered has been integrated in at the staff level. Annual review of the program will continue to assess trends and educational opportunities.

There was no public comment received regarding Strategic Goal 2.10

2.11 Review the role and responsibility of the PIC.

Chairperson Schaad stated that Senate Bill 476 (Stone) would have created a task force to study and submit a report to the Legislature on the prevalence of management interference upon the ability of pharmacists-in-charge to do their jobs and any legislative recommendations for improvement. SB 476 was held in Committee and Under Submission on May 16, 2019. No further action has been taken on this strategic goal.

Chairperson Schaad stated that the role of the PIC will be reviewed during discussions about disciplinary guidelines and during the development of language regulating corporate entities.

As part of the public discussion, the board was reminded that SB 476 is a 2-year bill.

Motion: Recommend to the board removal of Strategic Goal 2.6.
M/S: Sanchez/Lippe
Support: 4 Oppose: 0 Abstain: 0

13. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad informed the committee that they have been provided a copy of enforcement statistics reflecting the last full fiscal year.

Ms. Sodergren reported that pending cases are trending down. Additionally, three-year statistics would be provided at the next board meeting.

14. Future Committee Meeting Dates

Chairperson Schaad stated that the next committee meeting date is scheduled for November 5, 2019. As the board meeting dates for next year are finalized, additional dates will be posted on the board's website.

15. Adjournment

The meeting was adjourned at 1:08 p.m.