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

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE:	July 15, 2021
LOCATION:	Teleconference Public Committee Meeting Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-27-20, dated March 27, 2020, neither a public location nor teleconference locations are provided.
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member Chair Seung Oh, Licensee Member Vice-Chair Debbie Veale, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Eileen Smiley, DCA Staff Counsel Debbie Damoth, Administration Manager

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

Chairperson Maria Serpa called the meeting to order at 9:03 a.m.

DCA meeting moderator provided updated WebEx instructions.

Chairperson Serpa took Roll Call; a quorum was established.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda.

A member of the public asked for the status of the appointment of board member with compounding background to the Committee. In response, DCA Staff Counsel Eileen Smiley informed the Committee recruitment efforts are generally handled outside of the executive officer.

III. Approval of April 22, 2021, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes.

Motion: Approve the April 22, 2021 Committee Meeting minutes as presented.

M/S: Veale/Oh

Members of the public were provided with an opportunity to provide public comment; however, none were offered.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Serpa	Yes
Oh	Yes
Veale	Yes

IV. Discussion and Consideration of Committee's Strategic Goals

Dr. Serpa referenced the Committee's Strategic Goals included in the meeting materials. Members were invited to provide comments or ask questions on any of the goals. In addition, Dr. Serpa invited motions to provide recommendations to the board in order to update or change the Strategic Goals.

Member Veale requested clarification of goal 2.10. She asked for background information regarding the discussion of the role of the Pharmacist-in-charge (PIC) together with the Disciplinary Guidelines. EO Sodergren provided context that the PIC and Disciplinary Guidelines are being discussed together to explore whether the PIC is empowered with the appropriate authority to actually effectuate the changes necessary, within some environments, to comply with the law. In response, Dr. Serpa suggested a rewording of goal 2.10 to provide clarification. The committee discussed the overall intent of goal 2.10 in order to determine a clearer title for the goal.

Members of the committee were provided the opportunity discuss any other strategic goals; however, there were no additional comments by members.

Motion: Make a recommendation to the Board to change Strategic Goal 2.10 title to "Review the current status to ensure the PIC has the authority to meet the legal needs to be the PIC."

M/S: Veale/Oh

Members of the public were provided with an opportunity to provide public comment.

A member of the public suggested making the pharmacy owner or licensee responsible rather than the PIC.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Serpa	Yes
Oh	Yes
Veale	Yes

V. Presentation and Discussion on Board's Inspection Program

Dr. Serpa advised members that the Committee receives an annual presentation on the Board's Inspection Program.

Members received a presentation from Executive Officer (EO) Anne Sodergren. She stated inspections provide significant opportunity for education as part of the inspection process. The board established a policy goal to inspect all pharmacies every four years. While the inspection provides field inspectors the opportunity to observe and evaluate for compliance, it also provides an opportunity to educate and communicate with the licensee.

EO Sodergren reviewed the inspection process with the Committee, which include in large part, the observation and the practice and activity in that location. EO Sodergren continued by sharing a list of items reviewed. In addition, the inspector will also ask to see the information and confirm compliance with various aspects of Pharmacy Law. As the inspection progresses the inspector will inspect the condition of the physical plant, review security measures and overall cleanliness, and conduct an audit of expiration dates.

EO Sodergren explained that during the inspection there are opportunities for the licensee to ask questions. Board inspectors use this opportunity to educate

licensees on current laws. Current topics inspectors are covering with licensees are: COVID; Waivers that are in place; Current regulations in place; Warning Labels; Inventory Reconciliation and Self-Assessments. The Board strives to standardize the inspection procedure to ensure, at a minimum, all licensees have had the same basic items covered during the inspection process.

EO Sodergren stated Board staff performed over 2,800 inspections in FY 20/21. The Committee was informed that in-person inspections were suspended for parts of the year during various periods of COVID-19, as the conditions warranted. Board staff conducted desk audits to assess primarily sterile compounding and outsourcing facilities when the Board was unable to conduct physical inspections.

A breakdown of the different types of inspections was provided. The routine number represented those inspections that were not triggered by some other factor. EO Sodergren emphasized that it was important to note that in most cases, an inspection, irrespective of the triggering event, will encompass a routine assessment. She explained desk audit inspections were used to ensure that there was some level of assurance of compliance when the Board was unable to conduct onsite physical observation. Determining appropriateness of desk audits in lieu of onsite inspections were about what the conditions were at the time and balancing that information with the interest of patient care.

A breakdown of different routine inspection outcomes was provided. She noted no issues were found in 58% of inspected pharmacies; corrections orders were issued in 41% of inspected pharmacies; less than 2% were issued a Notice of Violation.

The following lists were provided to the Committee: A list of Top Ten Corrections on a Routine Pharmacy Inspections FY20/21, Top Ten Violations Notices on Routine Pharmacy Inspections FY 20/21 and Current Pharmacy Licensees Year of Last Routine Inspection.

EO Sodergren reviewed data relevant to findings during routine visits regarding violations of Duty to Consult. Data from the data set indicates consultation was not provided to a patient in 7 of 44 inspections. Further, in 37 of 44 inspections, the site was not providing written notice of consultation on delivered or mail order prescriptions.

A summary of current pharmacy licensees' year of last routine inspection was

presented. EO Sodergren explained that the Board has a policy goal to inspect all pharmacies at least once every four years; the summary provided data to show the Board's progress in meeting the goal. EO Sodergren highlighted that the Board has visited about 80% of all licensees that have been licensed since January 2013.

Members of the committee were provided the opportunity discuss the presentation or ask questions; however, there were no additional comments by members.

Dr. Serpa provided a reminder that the Board has available an education pamphlet on preparing for an inspection posted on the Board's website.

Members of the public were provided with an opportunity to provide public comment.

The Board inspectors were commended for conducting inspections during this pandemic year. Public comment recommended that a similar report be provided to members which includes clinics, wholesalers, outsourcing facilities, and other licenses not included in this current report. In response, EO Sodergren stated some of that information is included in the presentation, but staff can augment the report in the future at request of the Committee. Dr. Serpa added similar data is provided in Licensing Committee and Enforcement Committee statistics.

Public comment asked whether a sample inspection checklist will be available specifically for clinics that hold a clinic permit. In response, Dr. Serpa stated that more information for all license categories will be provided soon.

VI. Presentation and Discussion on Board's Citation and Fine Program

Dr. Serpa advised members the Committee receives an annual presentation on the Board's Citation and Fine Program.

Members received a presentation from EO Anne Sodergren. She informed the Committee that depending on the nature and severity of the violation, the outcomes can range from educating the licensee, issuance of a Letter of Admonishment, or the issuance of a citation. She stated when the Board takes a disciplinary action it is done under the provisions of the Administrative Procedures Act. EO Sodergren provided the reminder that a citation is not considered discipline.

EO Sodergren provided that most of the citations issued by the board are issued pursuant to Business and Professions Code section 4314. She explained that the

board uses its authority to issue citations to address important violations that are serious in nature but do not rise to the level of removal or restriction of a license through the administrative case process. She explained that staff use policy direction provided by the Board when making decisions on outcomes, including the levels of fines, noting that the board has indicated that the highest fines are really reserved for the most serious violations. In most cases the board is limited to a maximum of $5000 per investigation although there are some exceptions.

EO Sodergren explained to the Committee the factors considered in assessing administrative fines pursuant to CCR section 1775.2; these factors serve as guiding principles.

The citation process was reviewed. Once an investigation is completed and violation(s) had been substantiated the inspector submits the investigation report to a supervising inspector (SI)for review. Upon review by the SI, a recommended outcome is determined. The recommendation is forwarded for second level review where the chief of enforcement and executive officer meet to review the investigation and recommendation to ensure consistency. Cases with recommendations for the issuance of a citation are reviewed using this process. Citations can be issued with or without a fine or with or without an abatement. Once the citation is issued, the licensee has the opportunity to pay the fine, comply with an abatement order, or appeal the matter. If they opt to appeal, they can choose to have an informal office conference with Board representatives or go to a formal hearing with an Administrative Law Judge.

EO Sodergren provided historical data. She noted the number of fines issued, the amount of fines assessed, and the fines collected have all been trending down.

EO Sodergren shared the Boards processing times which indicated a significant increase over the past five fiscal years. She expects this number will decrease as staff vacancies are filled.

She reviewed orders of abatement and explained to the committee that compliance with an order of abatement typically results in either a reduction or forgiveness of a fine. EO Sodergren explained the different abatement types and how each type might be recommended. Data was provided detailing the total abatements issues and total abatements satisfied during FY20/21. Member Veale asked what percent of abatements, after removing licensees who opted to pay in lieu of abatement, are actually satisfied. EO Sodergren stated that specific data point would be collected and provide later. A list of violations that lend themselves to abatements was presented.

EO Sodergren stated licensees are always provided the opportunity to appeal. The informal office conference allows the opportunity to present additional or

mitigating information to the Board's Executive Officer or designee and an SI. In addition, a licensee may submit a formal appeal to the board within 30 days of issuance of a citation for referral to the Office of the Attorney General.

EO Sodergren provided data on citation appeal outcomes for FY 20/21, noting that data suggests participation in the office conference appeal can lead to modifications of the citation, reduction to a letter of admonishment or even dismissal.

EO Sodergren provided data on the top ten violations resulting in the issuance of a citation for pharmacies, pharmacists, interns and technicians for FY 20/21. Data was provided on citations issued specific to violations of Duty to Consult CCR section 1707.2.

Members of the committee were provided the opportunity discuss the presentation or ask questions; however, there were no additional comments by members.

Members of the public were provided with an opportunity to provide public comment; however, there no additional comments.

The meeting was in recess from 10:16 a.m. to 10:25 a.m. Roll call was taken. Members Maria Serpa, Debbie Veale, Seung Oh.

VII. Discussion and Consideration of Pre-filing Settlement Conference

Dr. Serpa reminded members during the last Committee meeting, the members considered an alternative case resolution proposal that could be implemented to reduce the time and cost associated with resolving a disciplinary matter. At that time, the committee expressed support for establishing a pre-accusation and settlement conference.

Dr. Serpa noted, since the last meeting, staff and representatives of the Office of the Attorney General have worked to further develop a general implementation plan as well as a flowchart that demonstrates what the process could look like. The flowcharts were included in the meeting materials.

Dr. Serpa presented, as proposed, the conference model will be used initially through cases assigned to the Board's two assigned Deputy Attorney Generals (DAG). The DAGs will work with Board staff to identify cases appropriate for this model.

Members of the committee were provided the opportunity discuss, ask questions or propose a motion to recommend this model to the Board.

Vice-Chair Oh requested clarity on whether the pre-filing case flow could serve as a settlement as well. In response, Ms. Smiley advised the pre-filing could be the opportunity to evaluate whether evidence is inappropriate and serve as a starting point for some type of settlement. However, Ms. Smiley stated a settlement cannot be approved until an accusation is filed. EO Sodergren clarified, in the pre-accusation conference model the investigation is completed, it has been determined that the violation(s) are egregious enough and warrants formal discipline, the matter is then referred to the Office of the Attorney General (OAG). At the OAG, the violations are assessed and confirmed. The DAGs then draft the pleading; before the pleading is filed the respondent is provided the opportunity to discuss and provide additional information to the DAG.

Member Veale stated that she envisioned the pre-filing settlement conference taking place before the matter is referred to the OAG.

EO Sodergren clarified that all disciplinary matters are referred to the OAG. Under this model the respondent is provided one additional opportunity, before the pleading is served to provide additional information or explanation.

Dr. Serpa clarified that once it has been determined by the Board that an investigation has resulted in a disciplinary action the matter must be forwarded to the OAG. In this model the pre-filing conference occurs after the matter has been forwarded to the OAG, but offers the respondent an opportunity to have further discussion outside of the interim process of the investigation to discuss the allegations to perhaps mitigate, remove or change the pleading. Additionally, Dr. Serpa informed the members that this model does not require statutory change, as directed by the Board.

Ms. Smiley informed the Committee that what the pre-filing conference is going to give the respondent is an opportunity to have a conference with the DAG before an accusation or statement of issues is made public and served on them. It gives the respondent the opportunity to potentially influence the DAG or convince the DAG assigned to the case that the allegation shouldn't be made before possible publicity.

EO Sodergren stated disciplinary matters which will be allowed use the pre-filing conference will be evaluated on a case-by-case basis. She cautioned that some cases will not lend themselves to this process, such as cases with eminent public harm or Category 4 which are of the most serious nature. This will be a learning process.

Motion: Recommend the Pre-Filing Settlement Conference model be forwarded to the Board for discussion and consideration.

M/S: Veale/Oh

Members of the public were provided with an opportunity to provide public comment.

Public comment suggested making the pharmacy owner or licensee responsible rather than the PIC.

A representative from California Pharmacists Association (CPhA) sought clarification on why a case is forwarded to the OAG and whether there are any instances, when discipline is being discussed, that does not involve a license being revoked, suspended, limited or conditioned? Ms. Smiley stated, with respect to how the Board generally operates, a pleading is required before any type of disciplinary proceeding can be instituted. On behalf of CPhA, he stated this process does not appropriately safeguard the rights that licensees have under the APA. He added, if statute forbids this conference before referral to the OAG, the CPhA recommends that the Committee table this discussion and this model not move forward to the Board.

Additional public comment requested supplemental information on steps that can be taken after the negotiation of the settlement. Options after a settlement is negotiated are to send it back to the Board for more investigation or the Board could withdraw the case. He believed showing these steps would show due process. He opined that this model is good but needs more work.

Public comment also stated that problems arise when DAGs are involved in the conversation. He requested that the conference include pharmacists, board members and/or board staff. He argued DAGs are not trained in the area of pharmacy.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Serpa	Yes
Oh	Yes
Veale	Yes

Discussion and Consideration of Board's Disciplinary Guidelines

Dr. Serpa informed members, the Board's Disciplinary Guidelines are incorporated by reference into Board regulation. As included in the Guidelines, the Board

provides the Guidelines for those involved in and/or affected by the disciplinary process including the general public, attorneys of the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, the courts, board staff and board members.

The Board provides that the Guidelines are to be followed in disciplinary actions noting that individual cases may necessitate a departure of the Guidelines, in such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision transmittal memo accompanying a proposed stipulation.

Dr. Serpa reminded the members during the April 2021 Board Meeting, it was recommended that the Board consider the current provisions as it relates to underlying actions involving Driving Under the Influence convictions. However, given the current Guidelines were previously adopted in February 2017, it may be appropriate to determine if a broader review would be appropriate.

Dr. Serpa advised members any changes that are recommended to the Disciplinary Guidelines must ultimately be made through the regulation process. She asked the Committee to also consider scheduling a dedicated meeting to complete their review.

Dr Serpa asked if it was the Committee's preference to limit the review of the Guidelines to specific areas. She provided examples of specific areas including penalty ranges for various categories of violations, types of violations and current category classifications, and nature and type of mitigation or rehabilitation.

Vice-Chair Oh expressed support of a broader review of the Disciplinary Guidelines since much has changed in pharmacy law since 2017.

Dr. Veale expressed support for limiting the review to specific areas. She stated that the Guidelines are flexible. She stated the current guidelines are well written and work very well.

Dr. Serpa stated she saw benefits of both reviewing in detail and leaving the guidelines as they are. She stated she would support a separate meeting to review the Disciplinary Guidelines.

Dr. Serpa asked as changes in the law have occurred since the Guidelines were most recently adopted, would it be helpful to the Committee if staff recommend changes to incorporate new licensing programs as well as recommend solutions to resolve conflicts between the Guidelines and other areas of Pharmacy law.

Dr. Veale suggested that Board staff should identify laws which are not addressed in the Guidelines.

Vice Chair Oh expressed his agreement at evaluating the Guidelines to incorporate new licensing programs. He agreed Board staff should identify laws which are not addressed in the Guidelines.

Dr. Serpa asked whether the Guidelines should be updated to incorporate a Letter of Public Reproval as a disciplinary outcome.

Vice-Chair Oh stated he did support the inclusion of a Letter of Public Reproval.

Dr. Veale suggested the Committee start with its review of incorporating new licensing programs and solutions; through that review process a Letter of Public Reproval might be considered.

Members of the public were provided with an opportunity to provide public comment.

Public comment was received to review Guidelines from the perspective of pharmacists. Secondly, he encouraged the consideration of a Letter of Public Reproval.

Another public comment stated that to add a Letter of Public Reproval to formal discipline would be a mistake. He stated a Letter of Public Reproval could cause negative implications on anyone with a license in another jurisdiction. This public comment supported a review of Guidelines at a special in-person meeting.

The committee concluded that a separate meeting to discuss and review Disciplinary Guidelines within Enforcement and Compounding Committee would be scheduled at a future date. Board staff will bring forward recommendations which would add value to the Guidelines for consideration. The committee stated an in-person meeting could be beneficial but was not required.

VIII. Discussion and Consideration of Authority for Pharmacists to Furnish Naloxone Hydrochloride, including the Protocol in Title 16, California Code of Regulations Section 1746.3

Dr. Serpa provided background information and reminded members, public comment was provided at the previous Committee meeting that suggested the current regulatory requirements could impede access. At this meeting, the Committee had the opportunity to review the legal requirements to determine whether changes should be recommended.

Dr. Serpa asked members if it was appropriate to request the Communication and Public Education Committee consider the development of educational materials.

Dr. Serpa informed the Committee the Board will convene a workgroup, pursuant to AB 1533, to consider if a transition to a standard of care enforcement would be feasible and appropriate. The Committee agreed the evaluation of this issue would be incorporated into the work of the workgroup.

Members of the public were provided with an opportunity to provide public comment.

Public comment was received which urged the Committee to consider the current opioid crisis, take a more immediate action and not wait for the standard of care process. He stated AB 1533 has not passed yet; after passage the workgroup would not be required to convene until July 2022.

Members of the committee were provided the opportunity discuss or ask questions.

Vice-Chair Oh requested, from the public, substantial information showing reasons or causes for the pharmacist to not be able to perform these duties. He asked for information to be sent to the Executive Officer.

EO Sodergren clarified that some may be overcomplicating the protocol. She shared board staff have indicated the protocol is appropriate.

Members of the public were provided with an opportunity to provide public comment.

Dr. James Gaspar was invited by the Committee to speak as a guest. He recognized the concern that some of the guidelines may be perceived as a barrier. Requirements including the training could be perceived as a barrier. He stated, in general, the process that is outlined in the guidelines is very consistent with what the standard practice would be. He opined the anecdotal reports may be overstating the complexity and the larger issue may be the stigma in the profession which may be keeping more pharmacists from participating. Dr. Veale asked if Dr. Gaspar thought a change in protocol was necessary to improve access. In response, Dr Gaspar informed the Committee that barriers could be decreased to improve access, but in his opinion the larger issue is pharmacist participation.

Public comment responded that training is not the problem; the issue is employers are not providing pharmacists the time to furnish Naloxone, pursuant to the current

protocol.

Dr. Veale stated that the problem may be getting pharmacists to offer Naloxone.

Public comment shared providers are providing Naloxone inhalers to the homeless population through Naloxone distribution programs set up by Department of Health Care Services (DHCS). Due to their limitation of not having pharmacist guidance, there may be issues with ensuring integrity of the Naloxone inhalers.

Dr. Gaspar stated there are no barriers in place that override the pharmacist's willingness to participate. The protocol requires patient engagement and pharmacists do not want to or are not comfortable with engaging with patients. He stated there could be improvements made to the protocol's efficiency, but it is not the real barrier.

Dr. Veale suggested that education to pharmacists would be beneficial.

The Committee recommended this information be forwarded to the Communication and Public Education Committee for the development of educational materials to assist pharmacists with understanding the value of Naloxone and how to make it part of their operation.

IX. Discussion and Consideration of Draft FAQs related to Regulations Governing Automated Drug Delivery Systems

Dr. Serpa reviewed the draft automated drug delivery systems (ADDS) FAQs with members.

Members of the committee were provided the opportunity discuss the FAQs or ask questions.

Both Dr. Veale and Vice-Chair Oh expressed satisfaction with the FAQs.

Dr. Serpa informed the Committee that Question 21 was updated and information was added. Dr. Serpa requested language clarification be added for hospitals that are using the service after hours, since it is not appropriate to use ADDS when the hospital pharmacy is open.

The Committee suggested the following language, "*Should your hospital provide*

discharge medications from the drug stock contained within an ADDS when the pharmacy is not open the board respectively requires your facility to secure licensure for each ADDS in that environment to be compliant with these requirements."

Motion: Recommend approval of FAQ consistent with the Committee's discussion and include the discussion into the FAQs in advance of the Board meeting later this month.

M/S: Serpa/Veale

Members of the public were provided with an opportunity to provide public comment.

Public comment was received requesting consideration to reevaluate Question 18 and Questions 21. He asked the Committee to take into consideration ADDS in smaller communities where there are limited resources. Additionally, he asked consideration be given to reevaluate the guidance given and reconsider the licensing requirement for ADDS.

Additional public comment stated the FAQ did not address whether an ADDS machine placed in a Board licensed clinic needs an ADDS license; the machine is for inventory tracking and nurses remove medication and not for directly dispensing medications to patients. She asked, will these types of machines require inspector visits and licensing prior to medication being stocked in the machine.

In response to the first public comment EO Sodergren stated the FAQs are a correct interpretation of the law. The development of the FAQs included input from supervising inspectors, counsel, and senior staff. The Board is strongly encouraging the goal to secure licensure compliance rather than strong enforcement.

In response to the second public comment, EO Sodergren suggested that questions be sent directly to the Ask Inspector line and board staff can provide guidance.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	**Vote**
Serpa	Yes

Oh	Yes
Veale	Yes

X. Review and Discussion of Enforcement Statistics

Dr. Serpa referenced the enforcement statistics provided in the meeting materials.

Members were provided the opportunity to provide comments; however, none were provided.

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

XI. Future Committee Meeting Dates

The Committee was reminded that the next Committee meeting is scheduled for October 20, 2021.

XII. Adjournment

Chairperson Serpa adjourned the meeting at 12:17 p.m.