California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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: October 27, 2020

LOCATION: Teleconference

COMMITTEE MEMBERS PRESENT:
Maria Serpa, Licensee Member Chair
Jignesh Patel, Licensee Member Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

STAFF MEMBERS PRESENT:
Anne Sodergren, Executive Officer
Norine Marks, DCA Staff Counsel
Eileen Smiley, DCA Staff Counsel
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth Admin. & Regulations Manager

1. Call to Order and Establishment of Quorum

Chairperson Maria Serpa called the meeting to order at 12:10 p.m. A quorum was established.

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

Chairperson Serpa invited public comment.

Members of the public requested the following items be placed on the agenda for future meetings: Discussion of the compounding of methylcobalamin; consideration of an additional meeting prior to the scheduled January 2021 Enforcement Committee meeting to discuss the Board's enforcement regarding the compounding of methylcobalamin; discussion regarding auxiliary warning labels; and discussion regarding the FDA's finalized Memorandum of Understanding regarding compounding.

Motion: Agendize discussion of compounding methylcobalamin for a future Enforcement & Compounding meeting.
M/S: Lippe/Veale
Support: 6 Oppose: 0 Abstain: 0

Motion: Agendize discussion of auxiliary labels to assist with naloxone accessibility for a future Enforcement & Compounding meeting.

M/S: Lippe/Veale
Support: 6 Oppose: 0 Abstain: 0

3. Discussion and Consideration of Recently Signed Legislation Impacting the Practice of Pharmacy

Chairperson Serpa referred members to copies of measures provided to each member prior to the meeting. Chairperson Serpa provided a review of recently signed legislation.

a. Assembly Bill 1710 (Wood, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines
The first measure for the committee's discussion is AB 1710.

Chairperson Serpa stated this measure provides pharmacists with the authority to independently order and administer FDA authorized or approved COVID-19 vaccines. She shared the committee had a support position on the bill.

The Chairperson acknowledged the recent immunization alert that was released by the Board strongly encouraged pharmacies, designated pharmacists-in-charge, and pharmacists to evaluate their practices of initiating and administering vaccinations and take immediate corrective action to ensure that their practices comply with regulations. She stated it was her understanding that a number of inquiries had been submitted via the Board's ask.inspector email address and to staff directly requesting that the Board evaluate scenarios to determine compliance. She explained, such an assessment must be done on a case by case basis by the pharmacy and its staff. She noted, it was her understanding that there is a wide range of processes being used. She suggested that if anyone sought clarification regarding whether their own current process complies the with law, they should consult with an attorney. Chairperson Serpa provided the following questions to help in the assessment of operations:

1. Who is writing the order for the immunization or directly ordering in the pharmacy system?
2. Who is interacting with the patient regarding health, allergy, and other information?
3. What functions are currently being performed by non-pharmacist staff and do any such functions require judgement?
4. To what extent is the pharmacist involved in the system process? Is it just at the point of administration?

Specific to AB 1710, Chairperson Serpa stated that she agrees that early education on the measure is important to ensure that pharmacists are well positioned to begin initiating and administering COVID-19 vaccines on January 1, assuming there is an FDA approved or authorized vaccine available.

There were no comments from committee members

A member of the public requested clarity regarding COVID-19 vaccination FDA

compliance and Advisory Committee on Immunization Practices (ACIP) approved protocols.

In response, Executive Officer (EO) Anne Sodergren clarified that pharmacists under their authority to provide immunizations in California may already perform this pursuant to BPC section 4052.8; therefore, their authority for ACIP already exists and the provisions are well established in California law and regulation. She explained AB 1710 expands the authority to also apply to COVID-19 vaccines that are either authorized or approved.

b. Assembly Bill 2077 (Ting, Chapter 274, Statutes of 2020) Hypodermic Needles and Syringes

Chairperson Serpa provided background information on AB 2077. She stated the bill extends provisions for needle exchange programs. She explained existing law provides authority for a pharmacy to furnish hypodermic needles and syringes for human use without a prescription under specified conditions, including knowledge that such furnishing are for a legitimate medical use. She stated, the section provides, that as a public health measure, such furnishing must also occur to prevent the transition of specified conditions, until January 1, 2021. Further, the section provides that as a condition of furnishing, a pharmacy must also provide information on access to drug treatment, access to testing information, and information on safely disposing of sharps waste. The bill extends the date to January 1, 2026.

Chairperson Serpa stated that she agreed that inclusion in the Pharmacy Law 2021 webinar was appropriate as well as inclusion in the Script. She did not believe additional action beyond that was required.

There were no comments from committee members.

There were no comments from the public.

c. Assembly Bill 2113 (Low, Chapter 186, Statutes of 2020) Refugees, Asylees, and Immigrants: Licensing

Chairperson Serpa provided background information on AB 2113. She stated that as detailed in the meeting material, AB 2113 will require the Board to expedite applications for an applicant who supplies satisfactory evidence to the Board that the applicant is a refugee, has been granted political asylum, or possesses a special immigrant visa.

She stated that in reviewing the information provided in the chair report, she did not believe this measure would have an impact from an enforcement perspective; however, she noted that staff will need to make changes to forms, etc. to implement. She added that staff also recommends developing an FAQ to provide guidance to applicants and as

implementation it may become necessary to promulgate regulations.

There were no comments from committee members.

There were no comments from the public.

d. Assembly Bill 3330 (Calderon, Chapter 359, Statutes of 2020) Department of Consumer Affairs: Boards: Licensees: Regulatory Fees

Chairperson Serpa provided background information on AB 3330. She stated that this measure increases the CURES fee that licensees pay to support the CURES System operated by the DOJ. The annual CURES fee will be $11 for annual renewals or $22 for licenses that renew biennially for a two-year period. The fees will then be reduced to $9/year or $18 for biennial renewals.

She stated her agreement with the implementation details in the chair report and would encourage the Board to send out reminders also as the implementation date gets closer.

There were no comments from committee members.

There were no comments from the public.

e. Senate Bill 878 (Jones, Chapter 131, Statutes of 2020) Department of Consumer Affairs Licensing: Applications

Chairperson Serpa provided background information on SB 878. She informed the committee that this measure requires the Board to post its application and renewal processing times.

There were no comments from committee members.

There were no comments from the public.

f. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)

Chairperson Serpa provided background information for SB 1474. She stated SB 1471 extends the Board's Sunset date for one year.

There were no comments from committee members.

There were no comments from the public.

4. Discussion and Consideration of Compounding Animal Drugs from Bulk Drug Substances,

Including Federal Law and the FDA Draft Guidance, #256

Chairperson Serpa reminded the committee that during the July Board meeting, the board received a request to agendize a discussion on this topic. The Chairperson stated she requested staff review the matter and determine if any changes had occurred in federal law. Subsequent to that, in late August, CPhA submitted a written request as well.

She stated, while there have not been any changes to federal law, this had been confused recently with the FDAs attempt to provide guidance and deserves discussion. Chairperson Serpa provided the background information. As indicated in the chair report, Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the compounding of an animal drug from bulk drug substances results in a "new animal drug" that must comply with the FD&C Act's approval, conditional approval, or indexing requirements (sections 512, 571, and 572 of the FD&C Act (21 U.S.C. §§ 360b, 360ccc, 360ccc-1)). Further, all animal drugs are required to be made in accordance with current good manufacturing practice (cGMP) requirement (section 501(a)(2)(B)) of the FD&C Act (21 U.S.C. § 351(a)(2)(B)) and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)). The FDA has historically exercised enforcement discretion with regards to animal drug compounding from bulk substances under circumstances when no other medically appropriate treatment options exist.

Chairperson Serpa also provided information on the FDA website which provides the following: Compounding Under AMDUCA, 21 CFR 530.13 provides specific conditions under which extralabel use from compounding of approved animal drugs or approved human drugs is permitted. The compounding must be in compliance with all relevant provisions of 21 CFR 530. The extralabel drug use regulation does not permit animal drug compounding from active pharmaceutical ingredients (bulk drugs); this is the current law.

Chairperson Serpa informed the committee, in November 2019, the FDA released for comment draft guidance for industry (GFI) #256, entitled, "Compounding Animal Drugs from Bulk Drug Substances." The FDA noted that the draft guidance, if finalized, would advise veterinarians on when the FDA does not intend to take enforcement action for certain violations of the FD&C Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk substances. The comment period for this draft guidance was extended on two occasions, with the most recent comment period expiring on October 15, 2020. Although still in its draft form, the draft guidance provides conditions under which the FDA states that it will generally exercise enforcement discretion for violations of the FD&C's requirements but it also notes that the Agency may take action when animal drugs are compounded from bulk drug substances that (1) present particular human or animal safety concerns or (2) do not meet other manufacturing, product, quality, labeling, or packaging requirements as required. The FDA notes that regardless of whether it intends to take action, the FDA may refer a case to the appropriate state entity. The draft guidance also states that FDA intends "to generally defer to State licensing boards for day-to-day oversight."

Chairperson Serpa stated that earlier this year, the Board received information about

compounding by California pharmacies using bulk substances, rather than sourced products from FDA approved drugs as required. In addition, the Board received information that pharmacies may be compounding from bulk substances, instead of from commercially available drugs, purportedly to reduce costs. To clarify this complicated issue, staff requested information from the FDA; the FDA's response is included in the meeting materials and includes much of the same information just provided.

Chairperson Serpa invited EO Sodergren to provide information about what board staff are identifying during inspections and how staff are currently handling the issues.

EO Sodergren informed the committee that as part of the Board's regulatory oversight of compounding facilities, the Board and its partner agencies are finding the marketplace to be non-compliant with federal law. She stated Board inspectors have been discussing federal requirements and, in some cases, issued Orders of Correction. An Order of Correction is not an "enforcement action", but typically requests the licensee to evaluate their practice and take the necessary steps to get into compliance. She stated that Orders of Correction usually require a licensee develop a Plan of Correction. The Board would then follow up with the corrective plans in 2021 as part of the Board's normal oversight. EO Sodergren stated there may have been some misunderstanding about the Board's actions thus far. She clarified the Board had not issued any Cease and Desist Orders or any similar action with respect to the inspections that had been conducted thus far.

DCA Counsel Eileen Smiley conducted research of current state of the law, the draft guidance and the information provided by the FDA. She stated the FDA has made clear that some of the different organizations who submitted letters disagree with the FDAs interpretation, but the FDAs interpretation is clearly set out so far. The draft guidance would demonstrate when the FDA intends to begin using its enforcement discretion. Ms. Smiley reiterated some of the supplemental associations disagree vehemently with the FDA and its interpretation of the Food, Drug and Cosmetic Act, but reminded the Board, Congress entrusted the interpretation and administration of this act to the FDA. The Board simply does not have the legal authority to dispute the FDA's interpretation.

Chairperson Serpa stated that she believed it is appropriate for Board staff to continue its educational efforts, orders of corrections and monitoring for compliance while balancing enforcement discretion and assessment of individual cases specific information to determine when additional action beyond education and orders of correction is appropriate. I believe this is not only consistent with the current actions being taken by staff but could also be viewed as consistent with the thinking of the FDA as we understand it.

Committee member discussion included concerns regarding whether or when the draft guidance will be finalized as well as when animal drugs are compounded from bulk drug substances when there is a medical necessity versus when there is a cost issue.

Public comment discussion included a request to the Board to reconsider the issuing of orders of corrections, opting rather to wait until a finalized guidance was approved. Additionally, there were two members of the public who expressed their disagreement with the draft guidance.

Motion: Board staff shall monitor this issue and keep the committee informed of emerging issues on the federal level, especially in regard to the draft guidance. The Board shall continue its educational role. The Board should evaluate situations on a case-by-case basis as they come up regarding this federal law.
M/S: Serpa/Wong
Support: 6 Oppose: 0 Abstain: 0

5. <u>Discussion and Consideration of the Use of Peptides in Compounding Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act)</u>

Chairperson Serpa provided background information. She referred committee members to information provided in the chair report which details the relevant Section 503A of the FD&C Act which describes the conditions under which a compounded drug product may qualify for an exemption from sections 501(a)(2)(B), 502(f)(1) and 505 of the FD&C Act. She explained those conditions include that the drug product is compounded by a licensed pharmacist in a state-licensed pharmacy or federal facility or by a licensed physician pursuant to a valid prescription for an identified individual patient that indicates the compounded drug is necessary for the identified patient. She stated, if the drug product is compounded using a bulk drug substance (active pharmaceutical ingredient) the bulk drug substance must: (1) comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, the bulk drug substance must be a component of an FDA-approved drug; or (3) if such a monograph does not exist and the drug substance is not a component of an FDA-approved drug, it must appear on the 503A bulks list. (Section 503A(b)(1)(A)(i) of the FD&C Act)

Chairperson Serpa stated that as indicated in the chair report, over the past several months staff has identified several pharmacies that are compounding using peptides. Board staff have confirmed with the FDA that many peptides are not eligible for the exemptions provided by section 503A of the FD&C as they do not satisfy the criteria for a bulk substance nor do they meet the conditions described in the "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act."

Chairperson Serpa informed the committee that Board staff continues to conduct investigations where appropriate. Further, staff is aware of pharmacies that have been issued 483 Observations by the FDA; these are inspection reports from the FDA noting observed violations.

Break: 1:25
Return: 1:36 Quorum established

6. Discussion and Consideration of Draft Information for Respondents Describing the Administrative Case Process

Chairperson Serpa reminded the committee of the presentation on the Administrative Case Process, offered at the last meeting. She stated following the meeting, it was suggested that it may be helpful to provide some general information to aid respondents in gaining a general understanding of the process and licensee's rights.

She stated for the committee's review, attachment 3 included draft frequently asked questions (FAQ) as well as a flow chart. If members agreed with the concept, she suggested that they recommend to the Board the finalization of the informational tool; this tool could be posted on the Board website. The Chairperson stated her interest in staff exploring the possibility of the AG's Office including this information as part information provided with the service of the documents.

Committee members agreed with the concept and were supportive of this method of educating licensees.

Motion: Finalize the Administrative Case Process Information Tools and distribute them.
M/S: Serpa/Lippe
Support: 6 Oppose: 0 Abstain: 0

7. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Chairperson Serpa stated members of this committee have had previous discussions regarding the potential of an alternative enforcement model to reduce both time and costs associated with resolving of a disciplinary matter. She informed, the original discussion was based on a model used by the Physical Therapy Board that provides an option for pre-pleading settlement of a matter where the outcome is public letter of reprimand. Details of the law granting the Physical Therapy Board such authority is in the Chair's report. Subsequent discussions included proposals to include two board members in the settlement process or to include an oral conference as a part of the process. At that time Board Counsel had concerns regarding these concepts and requested time to evaluate those suggestions. She explained, the committee has also recently received a presentation on the Administrative Case process. She continued, as was shared during that presentation, the administrative case process has two fundamental guiding principles: due process of the respondent and public protection. Deputy Attorney General Jarvis reminded the committee, the state has the duty and responsibility to ensure a licensee is competent and trustworthy.

Chairperson Serpa stated one of the concerns brought up during the public comment was that the administrative case process presented a perceived assumption of guilt. She clarified, there is no presumption of guilt after the filing of an Accusation. The board carries the burden of proof to establish a basis for discipline until that burden of proof is met. There is no presumption that the basis of discipline exists.

It is essential for the committee to be mindful of the state's responsibility as well as the policy goal the board is seeking to achieve by reducing time and costs associated with resolving a disciplinary matter.

Chairperson Serpa provided data provided in the Chair's report. She noted that over the past three years, only about 11% of substantiated investigations resulted in referral to the Office of the Attorney General. Additionally, 32% of the cases referred result in a default decision and 55% are resolved through a stipulated settlement. Only about 14% of the cases referred to the Office of the Attorney General actually go to an administrative hearing. Stipulated settlements appear to achieve the same the goal the Board is seeking through this alternative model, including risk avoidance, saving time and saving expense.

Chairperson Serpa wondered why the data also showed average processing times for stipulated settlements were greater than those set for hearing.

EO Sodergren explained there are pressure points in the administrative case process. When a matter is set for hearing, there is a pressure point because there is going to be a hearing scheduled. When a matter is not set for hearing because there's going to be a stipulated settlement, there may not necessarily be that same drive for resolution. In those cases, negotiations of a settlement can sometimes take longer and be a little more extensive especially if there is substantial negotiation.

Chairperson Serpa also presented another data point she found very interesting regarding the adopted versus nonadopted statistics. Based on the data presented, Ms. Serpa noted the Board is far more likely to nonadopt a proposed decision issued by an administrative law judge than a stipulated settlement negotiated by Board staff.

Ms. Smiley stated she reviewed the proposal considering what the current process is and where some pressure points could be. She stated one of the biggest concerns would be the involvement of board members because of the potential quorum issues that could develop later. Another concern was exactly how that hearing would be conducted. Would it be a paper process? What would be the impact be if a judgement or a settlement is not reached between the parties? It is those practical concerns, along with board member involvement that becomes potentially problematic. She then asked, if there was going to be a hearing component and they do not reach a judgment or settlement, then are they going to have two hearings? Would that just result in longer delays and greater cost? Particularly, who would administer an initial hearing? Who would determine the type of admissible evidence if there is an oral conference? How would the conference be treated if settlement is not reached?

Chairperson Serpa speculated about the requirements to participate in this alternative model and unintended outcomes. She stated a licensee would have to waive their rights to administrative adjudication and also admit to the allegation to participate in an alternative enforcement process. Any disagreement with the allegations would not qualify for the alternative model.

Secondly, if an agreement was not reached, this could result in additional time and cost for a second hearing in addition to the many legal issues that arise regarding the admissibility of the record. Additionally, if board members participate in alternative process that it could present a problem with the Open Meetings Act and may require those members to recuse themselves from future discussions if an agreement is not reached. It was also mentioned that board member presence may also require that a meeting becomes public.

Chairperson Serpa stated having discussed the background and some of the challenges that have been identified, she was interested in members thoughts about how the committee should proceed. Specifically, given the information received should they continue to move forward with development of an alternative enforcement model? Should the committee look more closely at the process used by the Physical Therapy Board, which is a very different and limited process? Should the committee take no action at this time?

Committee member discussion included inquiries regarding Physical Therapy Board's use of a letter of reprimands and when they are used. EO Sodergren informed the committee that the Board modeled its pre-pleading process from the Physical Therapy Board; the Physical Therapy Board has a range of outcomes like the Board's but have specific statutory authority to enter into an agreement where it's appropriate for a letter of reprimand as part of a pre-pleading settlement. Members expressed concern that this method may not resolve issues regarding costs savings.

Committee members asked DCA Counsel for clarification on when a stipulated settlement could occur. In response, Ms. Smiley stated, a stipulated settlement may occur any time after the filing of an accusation; it does not have to go to hearing. As with some of the stipulated judgements those will generally refer over to the accusation to give more context to the person signing it that they have fully and with knowledge waived their rights under the Administrative Procedure Act. It can occur at either time, but it occurs after the filing of the Accusation.

EO Sodergren informed the committee that investigations are conducted and reviewed by licensed pharmacists. Additionally, when expert knowledge is needed, the Board can hire via contract. EO Sodergren assured the committee that each investigator has pharmacy knowledge and cases referred to the Office of the Attorney General are the most egregious violations that could warrant removal or restriction of the license. She informed the committee when the case outcomes are reviewed and we look at the Board's actions specific to stipulations, Board members agree with the settlements that come before it for vote. EO Sodergren stated that this speaks to the fact that staff are executing stipulated settlements consistent with the Board's policy and its Disciplinary Guidelines and reflective of the collective decision of the Board.

Motion: No action at this time, but continue to evaluate the issue of the development of an Alternative Enforcement Model
M/S: Wong/Veale

Danny Martinez of CPhA requested that the committee's motion be withdrawn; instead he requests that this same item be placed on the next agenda and provide CPHa the opportunity to present a revised plan for consideration.

Two other members of the public expressed support of an alternative enforcement model.

In response to Mr. Martinez's request the motion was amended.

Motion: No action at this time but continue to discuss and evaluate the issue of the development of an Alternative Enforcement Model
M/S: Wong/Veale
Support: 6 Oppose:0 Abstain:0

8. <u>Discussion and Consideration of Proposal of Board's Policy Encouraging Pharmacies to Report to Law Enforcement Acts involving Drug Diversion by an Employee</u>

Chairperson Serpa stated during the January 2020 Board meeting, the Board approved a policy statement intended to encourage pharmacies to refer drug diversion cases to local law enforcement agencies for possible prosecution. Such referral would be in addition to mandatory reporting to the Board.

She stated the data provided in the meeting materials indicate that referrals to law enforcement are occurring; however, it may not be occurring with the frequency the Board would expect.

Motion: Recommendation to include the Board's policy statement in communications with licensees when seeking additional information regarding drug losses.
M/S: Serpa/Lippe
Support: 6 Oppose:0 Abstain:0

9. <u>Discussion and Consideration of Disciplinary Cases and Incorporation of the Ethics Program Requirement.</u>

Chairperson Serpa stated, the requirements for the ethics program are established in CCR section 1773.5. She informed the committee, recently the Board received a request to discuss what appeared to be a decrease in the number of disciplinary orders that include, as a condition of probation, completion of an ethics course.

She referred the committee to the information about the ethics program detailed in the chair report. She highlighted the program must include a minimum of 22 hours, at least 14 of which are contact hours and at least eight additional hours for preparation, evaluation, and assessment. She provided, the cost for the program offered by PBI Education is $1875. Also, calendar year data for those individuals that completed the PBI training is provided.

Chairperson Serpa stated that IMQ was another course provider but has recently closed.

Chairperson Serpa informed the committee the data in the chair report confirms that there has been a decline in the number of disciplinary orders that include, as a condition of probation, completion of an ethics course. EO Sodergren added that there are several respondents that now proactively complete the ethics course in advance of settlement and provide it as part of the mitigation. In those cases, it is not going to be included in the settlement because they have already completed the ethics course, which may be part of the reason for the decline.

During public comment it was stated that a possible reason for decline may be the high cost. It was suggested that ethics courses could be offered through a more affordable system such as a school/university system.

10. Review and Discussion of Enforcement Statistics

Chairperson Serpa reviewed enforcement statistics. She informed the committee since July 1, 2020, the board received 643 complaints and has closed 635 investigations. Additionally, as of October 1, 2020, the board currently has 1,345 field investigations pending. She directed the committee to review a breakdown on page 10 of the Chair's Report.

11. Future Committee Meeting Dates

Chairperson Serpa directed the members to the Chair's Report for future meeting dates.

12. Adjournment

Chairperson Serpa adjourned the meeting at 3:13 p.m.