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

# ENFORCEMENT COMMITTEE
# MEETING MINUTES

DATE: April 22, 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
Jig 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
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Administration Manager
Christine Acosta, Supervising Inspector

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

Chairperson Maria Serpa called the meeting to order at 12:30 p.m. Dr. Serpa advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Newsom's executive order. Members of the public were provided with general instructions for the WebEx meeting and process to provide public comments.

A roll call was taken. Members present included Jignesh Patel, Greg Lippe, Ricardo Sanchez, Debbie Veale, Albert Wong and Maria Serpa. A quorum was established.

## II. Public Comment 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; however, none were offered.

## III. Approval of January 20, 2021, Enforcement and Compounding Committee Meeting Minutes

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

**Motion:** Approve the January 20, 2021 Committee Meeting minutes, including the correction identified.

**M/S:** Lippe/Patel

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

**Support: 6 Oppose: 0 Abstain: 0 Not Present: 0**

| Committee Member | Vote |
|---|---|
| Lippe | Yes |
| Patel | Yes |
| Sanchez | Yes |
| Serpa | Yes |
| Veale | Yes |
| Wong | Yes |

**IV. <u>Approval of February 18, 2021, Minutes, Informational Meeting on "White Bagging"</u>**
Members were provided an opportunity to provide comments on the draft minutes.

**Motion:** Approve the January 20, 2021 Committee Meeting minutes, including the correction identified.

**M/S**: Veale/Lippe

Members of the public were provided with an opportunity to provide public comment. Members received a question from the public regarding the next scheduled discussion on the topic and was advised that the Committee will be providing an update to the Board during the Board Meeting.

**Support: 6 Oppose: 0 Abstain: 0 Not Present: 0**

| Committee Member | Vote |
|---|---|
| Lippe | Yes |
| Patel | Yes |
| Sanchez | Yes |
| Serpa | Yes |
| Veale | Yes |
| Wong | Yes |

**V. <u>Presentation on the National Association of Boards of Pharmacy, Compounding Data Sharing Project</u>**

Dr. Serpa advised members that the Chair Report detailed information on the conditions of the FDA MOU on Interstate Compounding and provided summary information including noting that the agreement establishes provisions for investigation of complaints relating to the compounded human drug products distributed outside of California, defines and establishes reporting requirements for the distribution of inordinate amounts of such products and mandates the submission and disclosure of information.

During our prior discussion, the Committee determined it would be beneficial to learn about the Information Sharing System developed by the National Association of Boards of Pharmacy (NABP) to facilitate some of the reporting and information sharing requirements established within the MOU.

Members received a presentation by Dr. Melissa Madigan, Associate Executive Director, Professional Affairs with the National Association of Boards of Pharmacy. Frances Gail Bormel, Acting Director, Office of Compounding Quality and Compliance with the Food and Drug Administration was also available to members for questions. (A copy of the presentation was included in the meeting materials.)

Dr. Madigan discussed the basic provisions of the MOU requirement and the state's obligations. Dr. Madigan discussed the provisions of inordinate amounts and provided background on the information sharing network developed by the NABP and its integration into the e-profile connect system.

Members were advised that the system will notify Boards about pharmacies whose data indicates they are distributing inordinate amounts and detailed the information that will be collected from the pharmacies. Members were advised how the system can facilitate the Board's obligation to notify the FDA the

requirements established in the MOU, including complaint information and that the system can also be used to fulfill reporting requirements for physician compounding to the FDA.

Ms. Bormel, FDA, stated that the system is a patient safety tool, and the importance of the MOU is the ability to share information centrally. Ms. Bormel noted the most pronounced patient safety tool is the adverse event report.

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

Members were also provided with the opportunity to provide public comment. Public comment requested clarification on the frequency required to report data and was advised that the MOU requires one-year worth of data, by calendar year. The system will accept data in 2019 and 2020 and NABP is anticipating annual submissions.

Public comment sought clarification if the system can segregate out veterinary compounding and was advised that pharmacies should not be reporting veterinary compounding. Further, the commenter was advised that the FDA is interested in learning about challenges states have with implementation.

## VI. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products

Following the presentation, Members proceeded with a discussion on the MOU. Members focused on larger policy questions including requesting confirmation from counsel if the Board had the authority to enter into the MOU. DCA Counsel Smiley confirmed that the Board does have the authority to enter into the MOU should it determine it can meet the obligations of the MOU. Ms. Smiley also noted that some confidentiality issues still require some additional evaluation.

The Committee discussed the potential benefits and negative impacts to California consumers if the Board enters into the agreement, noting that some pharmacies could choose to leave California if the Board does not enter the agreement, which could result in fewer options for California consumers, including those that require specialty items.

The Committee discussed the potential benefits and negative impacts to compounding pharmacies and residents outside of California if the Board does not enter into the MOU and noted the Board may lose its ability to regulate compounding as it currently does, and that specialty medication may not be available to patients in other states.

Members spoke in support of entering into the MOU.

Members of the public were provided with an opportunity to provide public comment. Public comment questioned if California should be reaching out the Medical Board. Ms. Smiley advised members that there is no requirement for the Board to request information from physician offices, rather just a reporting requirement if the Board becomes aware of the practice. A representative from McGuff referenced the petition submitted to the Board, encouraging the Board to sign the MOU and indicated that failure to sign could result in drug shortages.

Following the discussion on the larger policy issue, the Committee discussed policy questions related to implementation. Chair Serpa noted the meeting materials contained an example of a statutory frame work.

The Committee considered if the Board should require as a condition of renewal, that a pharmacy advise the Board that it distributes compounded preparations outside of California and determined such a requirement is appropriate.

After consideration, the Committee also determined that the Board should establish a requirement for such pharmacies to report sales to the Information Sharing Network as provided for in the MOU; noting such a requirement would make implementation feasible.

The Committee considered if the Board should establish a requirement for pharmacies to report adverse drug experiences and drug quality issues related to a drug compounded at the pharmacy; noting that as the Board is required to investigate such events, mandatory reporting is appropriate.

Members also considered if pharmacies that engage in interstate compounding should be required to affirm their understanding of the conditions of the MOU that must be fulfilled to engage in interstate compounding and concluded such a requirement is appropriate to ensure licensees have a full awareness of the requirements and obligations.

Members sought guidance from Ms. Smiley on the need to establish confidentiality provision to protect information sharing with the FDA. Ms. Smiley noted that agencies can share information through various methods.

Members also noted the importance of the Board developing educational materials for pharmacist that distribute products.

**Motion**: Recommend to the Board to move forward with draft statutory proposal including amending BPC 4110(a) and 4126.9 with change to 12 hours of notification and enter into the MOU provided sufficient resources and statutory changes are secured. Delegate to Executive Officer and Chair working with counsel to make nonsubstantive or clarifying changes.

**M/S**: Veale/Lippe

Members of the public were provided with an opportunity to provide public on the motion. Public comment suggested that the language be modified to clarify that the requirement only applies to human compounding.

**Support: 6 Oppose: 0 Abstain: 0 Not Present: 0**

| Committee Member | Vote |
|---|---|
| Lippe | Yes |
| Patel | Yes |
| Sanchez | Yes |
| Serpa | Yes |
| Veale | Yes |
| Wong | Yes |

*The meeting was in recess from 2:02 p.m. to 2:22 p.m. Roll call was taken. Members present: Jignesh Patel, Greg Lippe, Ricardo Sanchez, Debbie Veale, Albert Wong, Maria Serpa.*

**VII. <u>Discussion and Consideration of Compounding with Components or other Materials that Could Result in Insanitary Conditions as Established in the FDA Insanitary Conditions at Compounding Facilities Guidance for Industry</u>**

Dr. Serpa reminded members that the topic has been discussed several times over the course of the past few years and again more recently in detail at several meetings. Dr. Serpa noted the background information detailed in the meeting materials and noted the various resources and sources of information that surround this topic.

Dr. Serpa advised members that, as requested, staff discussed the issue with the FDA, who has confirmed that compounding from inappropriately graded products could result in violations of the guidance document regarding insanitary conditions. This would be consistent not only with the FDA alerts highlighting concerns with using dietary grade ingredients but also with the FDA 483 that was included in our prior meeting materials. Dr. Serpa continued advising members that NABP also recently confirmed that they share issues regarding inappropriately graded products with the state boards when identified.

Dr. Serpa provided information on the Board's ongoing education noting that educational efforts typically focus on provisions of the law, the importance of understanding the quality of ingredients prior to use, the importance of working with a supplier to improve the quality of bulk ingredients, to name a few.

Members of the public were provided with the opportunity to provide public comments. A representative from the California Pharmacist Association requested the Committee consider if additional testing would assist a pharmacist in determining and requested that the Board define a pharmaceutical grade ingredient.

Dr. Serpa noted that the Board needs to follow the information provided by the FDA. The educational materials provided during inspections were detailed in the meeting materials.

Additional public comment from Dr. Smith, stated that the FDA knows how needed methylcobalamin is and that the Board needs to protect access.

Dr. Serpa reiterated that the Board is focusing on providing education and in step with the FDA.

The Committee also received public comment from a compounding compliance officer speaking in support of the need for quality to be built into the entire compounding process.

Members concluded that no additional action is required, noting that staff will continue to educate and use enforcement discretion.

**VIII <u>Discussion and Consideration of Opportunities to Improve Naloxone Accessibility through Auxiliary Labels for Opioid Prescriptions</u>**

Dr. Serpa provided summary information on the agenda topic, noting that the meeting materials detail out the relevant laws and included a link to the Drug Safety Communication issued by the FDA. This communication recommends that health professions discuss the availability of naloxone. Members were reminded that this issue was added to the agenda following public comment at the October 27, 2020 meeting.

Members were provided with the opportunity to provide comments. Members noted that current labeling requirements are appropriate and that pharmacists providing appropriate consultation on a prescription for an opioid should include information on the use of naloxone. Members comments also noted that if the Board is interested in changes, it may be appropriate to consider establishing a requirement to dispense naloxone under specified conditions.

Members of the public were provided the opportunity to provide public comment. Comments provided suggested that the impediment to naloxone may be the requirements of the current protocol in place and indicated the Board could make such a change through Assembly Bill 1533. Other comments expressed concern if the Board were to establish a requirement for an additional auxiliary label.

Dr. Serpa advised members that a future agenda will include the opportunity for members to discuss the current naloxone protocol to determine if changes are appropriate.

**IX. Discussion and Consideration of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission**

Dr. Serpa advised members that in 2018 legislation was passed to facilitate e-prescribing, noting that the legislation included a delayed effective date to allow for a period of implementation and transition. As the provisions take effect January 1, 2022, the matter was agendized to allow the Committee the opportunity to consider if development of FAQs would be appropriate.

Dr. Serpa references the provisions of the legislation detailed in the meeting materials, noting there are a number of exceptions to the requirement and highlighting that a pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription falls within one of the exceptions.

Chair Serpa noted that it appears appropriate to consider if prescribing and dispensing medications within a single e-HR platform can be defined as "electronic transmission", versus sending prescriptions electronically to outside pharmacies.

After discussion, members determined development of FAQs and other educational materials should be referred to the Communication and Public Education Committee.

Members received public comment in support of the FAQs and noted that information on the provisions for transferring a prescription would be appropriate. Public comment also suggested that there may need to be an extension of the timeline for compliance with the provisions.

**X. Discussion and Consideration of Federal Food and Drug Administration Final Rule Related to Importation of Certain Canadian Prescription Drugs**

Dr. Serpa advised members last year the FDA finalized its rule to implement provisions of federal law that allow for the importation of certain prescriptions from Canada.

Members were provided a brief presentation on the federal requirements, including the requirements of an Importation Program Proposal, definitions of "eligible drugs",

"foreign seller" and "importer." Members were advised about provisions for FDA authorization as well as testing and recall requirements.

Members indicated it is appropriate to monitor this issue but that no action is required at this time.

Public comment was received suggesting that the State confer with Canadian colleagues before working to implement the provisions of the federal rule.

**XI. <u>Office of the Attorney General, Presentation on the Annual report to the Legislature Pursuant to Business and Professions code Section 312.2</u>**

Dr. Serpa introduced Carl Sonne, Senior Assistant Attorney General, with the Licensing Section of the California Department of Justice for his presentation.

Mr. Sonne provided background on the policy that resulted in the reporting requirements, including the Consumer Protection Enforcement Initiative, with the goal of reducing investigation and disciplinary timelines.

Mr. Sonne provided members with information on the data collection method used to develop the report. Mr. Sonne provided statistics from referrals for accusations, include the number of referrals, number of cases rejected by the Attorney General's Office, the cases returned for further investigation, and number of cases adjudicated.

Mr. Sonne summarized Board specific information and concluded noting that with data you can measure outcomes.

Members were provided with the opportunity to provide questions but did not have any.

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

*Meeting was in recess from 3:48 p.m. to 3:58 p.m. Roll call was taken. Members present: Jignesh Patel, Greg Lippe, Ricardo Sanchez, Debbie Veale and Maria Serpa. Member Wong returned at 4:20 p.m.*

**XII. <u>Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model</u>**

Dr. Serpa referenced the relevant provisions in the law included in the meeting materials and reminded members that as part of the July 2020 meeting, a presentation was provided on the administrative case process. As was shared during that presentation, the administrative case process has two fundamental guiding principles: due process of the respondent and public protection. As part of

the presentation, members were reminded that the state has the duty and responsibility to ensure a licensee is competent and trustworthy.

Chair Serpa advised members that during the prior discussion, members directed staff to develop recommendations to achieve the policy goal to reduce case resolution times and reduce associated costs, that would not require statutory changes. Dr. Serpa referred members to the meeting materials including information on a pre-accusation conference that is used by the Board of Accountancy and a model used by the Department of Managed Health Care (DMHC). Dr. Serpa noted that a transition to the full model used by DMHC would require statutory changes.

Members considered the pre-pleading conference and several policy questions related to the proposed solution. As part of its discussion members noted that the pre-pleading conference appeared to be a good solution and noted support of the concept.

Members also noted that such a conference may not be appropriate for all cases and that the model did provide an appropriate balance of consumer protection and due process. Members also determined that use of such a process could reduce case resolution times and that the process could result in cost savings for the Board and for licensees.

Mr. Sonne advised members that the AG's office considers the pre-pleading conference of great value because it provides an opportunity for the licensee to provide additional information. Mr. Sonne noted, that if agreement is reached with the parties, it can front end the settlement after the accusation is filed. Mr. Sonne noted that not all cases may be appropriate for this process.

In response to member questions, Mr. Sonne advised the Committee the licensee and their representative, if applicable, participate in the pre-pleading conference.

**XIII. <u>Review and Discussion of Enforcement Statistics</u>**

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

Members were provided with 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.

**XIV. <u>Future Committee Meeting Dates</u>**

The Committee was reminded that the next Committee meeting is scheduled for July 15, 2021.

## XV Adjournment

Chairperson Serpa adjourned the meeting at 4:19 p.m.