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

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE: January 27, 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
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth Admin. & Regulations Manager

I. Call to Order and Establishment of Quorum

Chairperson Maria Serpa called the meeting to order at 9:01 a.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 Greg Lippe, Jignesh Patel, Ricardo Sanchez, Albert Wong, and Maria Serpa. A quorum was established.

II. Public Comment on Items Not on the Agenda, Matters 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 October 27, 2020, Enforcement and Compounding Committee Minutes

Members were provided an opportunity to provide comments on the draft

minutes. Members noted the need to correct reference to CPhA.

Motion: Approve the October 27, 2020, Committee meeting minutes including the correction identified.

M/S: Lippe/Wong

Members of the pubic were provided an opportunity to provide comments; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Not present
Wong	Yes

IV. Presentation on the Pharmacists Recovery Program

During the meeting members received a presentation on the provisions of the Pharmacists Recovery Program (PRP). The presentation can be viewed as part of the webcast of the meeting posted on the Board's website.

Members were advised that the program was established in statute to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The statute also provides that the intent of the program is to return pharmacists and interns to the practice of pharmacy in a manner that will not endanger the public health and safety. Consistent with the provisions of the statute, the Board contracts with a qualified vendor to administer the program. The current contractor is MAXIMUS, Inc.

The presentation was provided by Virginia Matthews, Project Manager, for Maximus, California Health Professionals Recovery Program. During the

presentation Ms. Matthews, provided an overview of the program, including other DCA programs also under contract with Maximus for services.

Ms. Matthews provided an overview of alcoholism and addiction as well as the signs, symptoms and impact of substance abuse in the workplace. Ms. Matthews discussed the risks for healthcare professionals, noting that because of accessibility to controlled substances, are especially susceptible to substance use disorder. Ms. Matthews provided an overview of the recovery program highlighting the two primary goals of the program include protection of the public and returning healthcare professionals to safe clinical practice, through intervention and rehabilitation. Ms. Matthews reviewed program eligibility requirements and contractual performance requirements as well as general provisions for participation, including criteria for returning to work and the transition phase prior to completion.

Member Veale joined the meeting around 9:30 a.m.

At the conclusion of the presentation, members of the public were provided with an opportunity to provide public comment.

A representative from the California Society of Health Systems Pharmacists (CSHP) suggested that the PRP should be opened to pharmacy technicians and encouraged a future agenda item to discuss the opportunity to make such a change.

No action was taken on this item.

The meeting was in recess from 10:20 a.m. – 10:30 a.m. Following the recess roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale, Maria Serpa. Albert Wong was not present during the roll call.

V. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines

Chair Serpa, lead the committee in resuming its discussion on the Committee's evaluation of the Board's disclosure policy for citations and fines. Dr. Serpa referenced information included in the materials, noting that in July 2018, the Board referred this matter back to the committee for further consideration.

Member Wong returned to the meeting at 10:33 a.m.

As part of its discussion, the committee considered several policy questions including discussion on the larger policy goal of the Board. Members noted that the Board's current policy goal is to provide transparency on disciplinary actions

and noted the difference between disciplinary actions and citations. The committee drew a distinction between the two noting that routine citations or fines that may come up during routine inspections or investigations of complaints do not merit discipline.

Members noted that the Board's current policy is consistent with its consumer protection mandate and ensures the public is aware of discipline, while also releasing citations in response to requests for information.

Members also expressed concern with a potential change to the policy that would require posting of citations on the Board's website, noting such a change could have a chilling effect and unintended consequences, including the potential inference that a citation is discipline.

Members of the public stated agreement with committee discussion noting that non-disciplinary action should not be posted and described some unintended consequences including a misunderstanding of what the action represents.

No action was taken by the committee.

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

During the meeting members reviewed proposed changes to self-assessment forms. Chairperson Serpa and members discussed the importance of the self-assessment process, which is intended to be an education and self-monitoring tool for licensees to evaluate for compliance. Members were reminded that failure to complete the self-assessment form is among the top 10 violations identified during a routine pharmacy inspection.

Members also discussed the self-assessment process and considered if changes would be beneficial. The committee suggested additional opportunities for education on the requirements to complete the self-assessment forms, including additional opportunities to remind licensees of the requirements. The committee determined that further discussion on the process appears is appropriate and suggested that such discussion would be appropriate under the purview of the Communication and Public Education Committee.

Members first considered the proposed changes to the Community Pharmacy/Hospital Out-Patient Self-assessment form 17M-13. The committee reviewed the changes.

Motion: Accept the updated self-assessment forms with corrections to typographical errors as necessary.

M/S: Veale/Lippe

The members were advised through public comment that self-assessment forms are used as an educational tool for student in pharmacy school.

Support:6 Oppose:0 Abstain:0

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

Members also considered proposed changes to the Community Pharmacy and Hospital Out-Patient Pharmacy Compounding Self-Assessment Form 17M-14. The committee reviewed the changes, noting that the recommendation includes a repeal and replace of the self-assessment form.

Motion: Recommend initiation of a rulemaking to amend section 1735.2 of California Code of Regulations to update the Community Pharmacy and Hospital Out-Patient Pharmacy Compounding Self-Assessment Form 17M-14.

M/S: Lippe/Veale

Public comment sought clarification on the provisions related to temperature requirements included in regulation section 1751.4(k). Staff indicated the referenced section would be reviewed and corrected, as appropriate.

Support:6 Oppose:0 Abstain:0

Committee Member	Vote
Lippe	Yes
Patel	Yes

Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

Members also considered proposed changes to the Hospital Pharmacy Self-Assessment form 17M-14. The committee reviewed the changes.

Motion: Accept the updated self-assessment form with corrections to typographical errors as necessary.

M/S: Veale/Lippe

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

Support:6 Oppose:0 Abstain:0

Committee Member	**Vote**
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

The committee deferred its consideration of the changes to the Wholesaler Dangerous Drugs and Devices Self-Assessment and Automated Drug Delivery Systems Self-Assessment.

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

Chairperson Serpa referenced information in the meeting materials including history of the committee's discussion on this issue. Further, Dr. Serpa reminded

the committee of the presentation it received in July 2020, 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. Dr. Serpa noted that Deputy Attorney General Jarvis included as part of the presentation that the state has the duty and responsibility to ensure a licensee is competent and trustworthy.

Dr. Serpa reminded members that more recently, during the October 2020 meeting, the committee continued its discussion on an Alternative Enforcement model but did not reach a conclusion. The committee determined that additional consideration of the overall policy goal and proposed solution would be appropriate.

Members noted the need to make a decision based on data as opposed to responding to anecdotal information. Further, members were reminded of counsel's previous guidance that a licensee seeking to challenge the factual matters or the application of law to the facts should use the process under the administrative procedure act.

It was also noted that an alternative process is not possible under current legislative authority. Counsel previously raised a number of concerns about the potential for a preliminary hearing, including evidentiary issues and open meeting act considerations previously contemplated. Additionally, concerns were identified with Board members participation in the settlement process.

Members also referenced educational materials under development including FAQs and a Flow Chart on the administrative case process that could be published on the Board's website and included in the mailings to assist respondents in understanding the process and their rights.

Members of the public were provided the opportunity to provide information on proposals for an alternative enforcement model.

Daniel Martinez, CPhA, provided information in advance of the meeting which was provided to members and posted on the Board's website. The proposal offered by CPhA included changes to a proposal previously considered, but not accepted by the committee.

The committee also received public comment from Joseph Gracela, who indicated that Board members need to participate in the process to have oversight and transparency.

The committee noted that the issue is complex. Members discussed what problem was being solved noting a challenge because the problems

articulated through public comment appeared subjective, not objective. The committee indicated that benchmarking with other agencies might be helpful. The committee also indicated that a presentation on the investigation process would be helpful.

Members requested staff return to the committee with recommendations that would not require legislative changes.

The committee did not take action on this item.

The meeting was in recess from 12:45 p.m. – 1:15 p.m. Following the recess roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale, Maria Serpa and Albert Wong.

VIII. <u>Discussion and Consideration of Discrepancies Between the State and Federal Controlled Substances and Its Impact on Healthcare Services.</u>

Chairperson Serpa noted that the meeting materials provided a history of the Board's recent policy discussion on the issue, including prior legislative efforts. Dr. Serpa indicated that as discrepancies remain between the state and federal schedules, it is appropriate for the Committee to consider whether additional efforts should be undertaken to synchronize or otherwise address the discrepancies.

The Committee considered policy questions that were also displayed during the meeting. Chairperson Serpa suggested it was important for four specific drugs to be considered noting that Fioricet, Donnatal, Librax and Chlordiazepoxide were all included in the state schedule but not scheduled under federal law.

Motion: Recommend to the full Board that California match the federal schedule for the 4 identified drugs – Fioricet, Donnatal, Librax and Chlordiazepoxide. This would require legislative authority.

M/S: Lippe/Veale

Dr. Gray, representing CSHP, was concerned with the motion because it did not solve the problem. Dr. Gray suggested as an alternative, the committee consider using the schedules for different purposes, the state schedule for criminal purposes and the federal schedule for patient care systems**.**

Support:6 Oppose:0 Abstain:0

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

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

Chairperson Serpa reminded the committee that in October 2020, the FDA finalized its draft Memorandum of Understanding (MOU), that established an agreement between the respective state authority and the FDA regarding the interstate distribution of inordinate amounts of compounded human drug products.

Dr. Serpa noted 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. Dr. Serpa informed the committee members that they received the supplemental meeting materials that included comments on this agenda item.

Dr. Serpa stated that she believed this is a very complex issue which cannot be resolved in a single committee meeting. She noted that staff has identified some significant challenges with the MOU and that counsel evaluated the MOU for legal issues. In the meeting materials provided, she noted two states had already decided not to enter into the MOU, and several other jurisdictions were still undecided.

Dr. Serpa asked DCA Counsel Smiley to provide the committee with her assessment of the legal issues surrounding the MOU.

Ms. Smiley stated that she was still in the process of reviewing the MOU, but at this point of her review she had concerns regarding confidentiality. Ms. Smiley indicated that the Board could not sign the MOU currently because it did not

have the required reporting mechanism in place. Ms. Smiley informed the committee that the Board has until October 2021 to make the necessary changes.

During public comment Daniel Martinez, CPhA, provided his support for the Board signing the MOU. Three representatives from Nutrishare also expressed their support of the Board signing the FDA's MOU. Ms. Christy Poindexter, TPN consumer, expressed her support of the board signing the MOU.

Dr. Serpa acknowledged the time constraints and the need for further discussion. The committee directed board staff request the National Association of Boards of Pharmacy (NABP) to provide a presentation on the Information Sharing Program at the next committee meeting.

The committee did not take action on this item.

X. Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry

Chairperson Serpa informed Committee Members, this issue was discussed in depth during the October committee meeting. She stated, under the Food, Drug, and Cosmetic Act, a drug is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions.

Dr. Serpa referred members to Attachment 6 of the meeting materials that included a copy of the guidance document. As indicated in the guidance document, the FDA encourages states to take appropriate action and to contact the FDA when it identifies a compounding facility that is engaged in poor practices and/or where insanitary conditions are identified.

The Committee heard public comment from Rod Okamoto, Nutrishare, who spoke about the federal inspection process; Ronald McGuff, of McGuff Pharmaceuticals, who suggested that the relevant sections of USP could be used to define "pharmaceutical grade"; and Danny Martinez, of CPhA.

The committee did not take action on this item.

XI. Discussion and Consideration of the Compounding of Methylcobalamin

Chairperson Serpa reminded members of previous discussions surrounding the compounding of methylcobalamin including as part of previous Compounding Committee meetings regarding USP Standards and impacts to Board compounding regulations. Dr. Serpa specified during those meetings, the Board has consistently pointed patients to potential sources to obtain such products. Dr. Serpa also referenced, Attachment 7 of the meeting materials with included

an example FDA 483 report which documents observations of a facility using non-pharmaceutical grade Methylcobalamin to compound sterile product.

Dr. Serpa noted other provisions must also be considered, specifically the compounding of Methylcobalamin, including the conditions described as constituting insanitary conditions the Committee discussed in the prior agenda item.

Dr. Serpa stated her belief that the FDA's position on the issue appeared clear from the public information it released and noted that from a patient safety perspective, the Board needs to balance product access with product safety.

Dr. Serpa specified one of the primary challenges experienced by some compounding facilities, is the lack of pharmaceutical grade Methylcobalamin. Inappropriately graded materials can contain lead, arsenic, and other compounds which create risk to patients when used in sterile products. Long-term it would be beneficial for one or more manufacturers to either produce pharmaceutical grade bulk ingredients or seek approval from the FDA.

As part of the Committee discussion, Member Veale expressed her concern regarding quality of product being compounded at 503A compounding pharmacies. President Lippe inquired as to supply shortages of Methylcobalamin.

Dr. Serpa stated that she believed moving forward, staff should focus on educating licensees and exercise appropriate enforcement discretion.

The Committee heard public comment from several members of the licensed community as well as from private consumers.

Daniel Martinez, CPhA spoke against prohibiting pharmacies from producing Methylcobalamin. In relation to statements made, EO Sodergren offered to work with DCA counsel offline to confirm the state of affairs with respect to outsourcing facilities distributing in California.

Ms. VanNess, a parent of a child currently using Methylcobalamin, testified she fears neuropsychiatric deterioration consequences if her son is no longer able to obtain Methylcobalamin.

R. Israel, professional and general counsel of a compounding pharmacy, spoke against limiting ability of 503A pharmacies to compound sterile Methylcobalamin injections.

Dr. Becker spoke of his experience and success in using Methylcobalamin in functional psychiatry for the past 15 years. He warned of costs becoming prohibitive and inaccessible to patients.

Mr. Pham, McGuff Pharmacies, spoke to methods of screening incoming material for the level of elemental impurities; he stated these tools are not unique to 503B outsourcing facilities.

Dr. Ashby spoke to her patients' extensive experience of using injectables. She states it has become progressively more difficult to find pharmacies that are still producing them.

Ms. Gardner urged the Board to allow pharmacies to compound Methylcobalamin. Based on her own experience using Methylcobalamin shots, this medication prevents her from having to take 11 pain pills per day.

Dr. Holstead spoke about his experience working with autistic children and people with mixed connective tissue disease. He shared that 25 of his patients were successfully using Methylcobalamin but he can no longer get the concentration he needs because the one pharmacy he used has shut down due to regulatory restrictions. He is unable to find any pharmacies that will produce Methylcobalamin.

Dr. Osbourne spoke to the benefits of Methylcobalamin compounded by pharmacies. She explained that the benefit of compounding by pharmacies is that only the specific amount needed is produced. Additionally, she remarked that costs would increase exponentially if pharmacies were not allowed to compound.

Dr. McGuff, McGuff Pharmacies spoke to a pharmacy's ability to review pharmaceutical grade raw materials. He encouraged the Board to use the generated reports created by independent FDA registered laboratories as evidence whether a pharmacy is using a pharmaceutical ingredient.

Ms. Alexander, parent of child who uses Methylcobalamin and a patient herself, testified to the success of using the injectables. She and her child have both used the product successfully for five years with no side effects.

Ms. Robinson, parent of an autistic child who could not speak at the age of 5, stated the day after his first injectable dose of Methylcobalamin, her son was able to speak. Now 18, her son continues to need preservative-free shots, which she does not believe can be obtained from an outsourcing facility.

Jillian, parent of an autistic son testified her son was non-verbal until almost 4 years old. After he started compounded Methyl B12 injections he started making noises and by 4½ years old he was speaking basic sentences. Her son's cognitive awareness and overall health greatly improved as a result of the Methyl B12 injections. Jillian believes without compounded Methyl B12 her son's condition would regress and he would become low-functioning.

Ms. Fingerhood spoke about product testing and asked board to engage 503A pharmacies with additional end-product testing recommendations.

Dr. Koshland spoke about his difficulty in finding outsourcing facilities to serve his patients who compound B12. He testified, out of 29 outsourcing facilities he researched, he only found one who supplied B12 in limited strengths, for office use only and preservative free. He informed the committee in his experience there are no outsourcing that can meet the needs of many patients that have specific needs, such as preservative free or specific strength.

A representative speaking on behalf of the National Community Pharmacists Association urged the board to acknowledge the need to maintain patient specific compounding of Methylcobalamin through pharmacies. He urged the committee to not set an unsettling precedent for the rest of the country.

Member Patel left the meeting at 2:03 p.m. and returned at 2:51p.m.

Dr. Serpa indicated that moving forward staff should continue to educate and exercise appropriate enforcement discretion. She recommended staff should also continue to review information from the FDA.

Member Wong thanked the professional and patient community for their feedback.

XII. Review and Discussion of Enforcement Statistics

Members were directed to the enforcement statistics in the meeting materials.

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

XIII. Future Committee Meeting Dates

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

Additionally, Dr. Serpa announced proposed meeting dates for an informational meeting on White Bagging, to be held either February 18, 2021 or March 4, 2021. Members of the public were directed to contact Executive Officer Sodergren if interested in providing a presentation during the meeting.

XIV. Adjournment

Chairperson Serpa adjourned the meeting at 3:20 p.m.