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

ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: April 13, 2023

LOCATION: Department of Consumer Affairs
1625 N Market Blvd, 1st Floor Hearing Room
Sacramento, CA 95834

Participation was also through WebEx.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member
Ricardo Sanchez, Public Member

COMMITTEE MEMBERS NOT PRESENT: Jig Patel, Licensee Member, Vice Chair

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at approximately 9:00 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensee Member. 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 suggested another entity do the inspections for all of the California non-sterile compounding pharmacies and all of the out-of-state 503A compounding pharmacies. The commentor suggested licensees disclose as part of the renewal if they perform nonsterile compounding. If disclosed, an inspection would be required.

Members were surveyed to see if any items should be added to a future agenda; however, no comments were made.

III. Approval of March 23, 2023, Enforcement and Compounding Committee Meeting Minutes

Chairperson Serpa referenced the draft minutes for the March 23, 2023, Enforcement and Compounding Committee Meeting.

Members were provided an opportunity to provide comments on the draft minutes; however, no comments were made.

Counsel Smiley requested being removed as having attended the meeting as Ms. Smiley was not present.

Motion: Approve the March 23, 2023, Committee Meeting Minutes as presented in the meeting materials with the correction of removing Counsel Smiley in attendance at the meeting.

M/S: Oh/Barker

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided in Sacramento or via WebEx.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Not Present
Sanchez	Not Present
Serpa	Support

IV. Presentation on USP General Chapter 800, Regarding Hazardous Drugs – Handling in Healthcare Settings

Chairperson Serpa introduced Supervising Inspector Ana Kalantar who provided a presentation on the revised USP Chapter 800 related to Pharmaceutical Compounding – Sterile Preparations which become effective November 1, 2023.

Supervising Inspector Kalantar provided a presentation on USP General Chapter 800, Regarding Pharmaceutical Compounding – Sterile Preparations. Dr. Kalantar provided a disclaimer regarding the opinions expressed in the presentation. Dr. Kalantar provided an overview including Introduction and Scope; List of Hazardous Drugs; Types of Exposure; Responsibilities of Personnel Handling Hazardous Drugs; Facilities and Engineering Controls; Environmental Quality and Control; Personal Protective Equipment; Hazard Communication Program; Personnel Training; Receiving; Labeling, Packaging, Transport, and Disposal; Dispensing Final Dosage Forms; Compounding; Administering; Deactivating, Decontaminating, Cleaning and Disinfecting; Spill Control; Documentation and Standard Operating Procedures; and Medical Surveillance.

The Committee took a break from 9:34 a.m. to 9:40 a.m. Chairperson Serpa took roll call after the break. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

Members were provided the opportunity to comment.

Chairperson Serpa commented under 532 Sterile Compounding when negative pressure was discussed between 0.01 and 0.03 that was -0.01 and -0.03 (negative

values). Dr. Serpa requested the slides be updated for the benefit of people reviewing the slides after the presentation.

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

V. Discussion and Consideration and Possible Action on Proposal to add New Titles and Sections 1737-1738.18 to Article 4.7 of Division 17 of Title 16 of the California Code of Regulations Related to the handling of Hazardous Drugs

Chairperson Serpa advised as the Committee continued work on reviewing the various USP chapters and review current and proposed regulations that may be necessary to implement, clarify, or make more specific requirements related to those respective chapters, Dr. Serpa believed it was appropriate that any such regulations mirror the structure of the respective chapters. This meant the numbering format and section titles for proposed regulations would mirror the USP chapter. Dr. Serpa clarified the goal was not to re-iterate provisions of federal law or USP language but to clarify or make more specific the requirements. Dr. Serpa noted if no clarification was needed or no additional requirements were necessary for public safety, no additional language was being proposed.

Chairperson Serpa reminded participants that the Board is a consumer protection agency. Dr. Serpa advised during development of regulations, it would be through the lens of the Board's consumer protection mandate as the law makes clear whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Serpa recalled it was a dynamic process and individuals would have opportunities to participate throughout the development and rulemaking process.

Chairperson Serpa noted licensees of the Board generally must comply with a myriad of state and federal laws and at times, a licensee may be so focused on a specific section of the law, that they may forget the larger picture and other provisions of law that may be relevant. Dr. Serpa noted this was seen in several areas of pharmacy practice, but it was quite pronounced in compounding.

Chairperson Serpa reminded participants of the excellent overview Counsel Eileen Smiley provided during our January 2023 meeting covering the requirements for authorized individuals to qualify for some exemptions to federal law under provisions of section 503A. Dr. Serpa added the livestream of the meeting and the presentation slides were available on the Board's website. Dr. Serpa encourage individuals interested in this area to watch the livestream recording available from the Board's website. Dr. Serpa reiterated:

- The Committee would not be looking to add to regulations requirements already laid out in the USP chapters or federal law. The Committee was generally focused on detailing additional California state requirements related to the changes to the USP chapters.
- The discussions would be dealing with the standard for compounding pharmacies and compounding pharmacists operating in compliance with the exemption in Section 503A of the federal Food Drug and Cosmetic Act and not with 503B or outsourcing facilities.

Chairperson Serpa noted Section 503A was quite extensive, but felt it was appropriate to highlight that one of the specific conditions a licensee must meet to be eligible for the exemptions provided under 503A is that the drug product is compounded in compliance with USP chapters on pharmacy compounding. It was important that members and stakeholders understand prior to the discussion. Business and Professions Code (BPC) section 4126.8 explicitly states the Board has the authority to enforce any USP Chapters where incorporated by reference in Pharmacy Law and its regulations. Dr. Serpa clarified the Board can also add additional requirements to USP language but cannot promulgate a lesser standard in its regulation.

Chairperson Serpa noted that comments were received and posted on the Board's website; however, comments were appropriate for consideration during the April 2023 Board Meeting as the information was not on the Committee's agenda.

Chairperson Serpa reviewed the process for the meeting. Dr. Serpa requested staff display the language during the portion of the meeting to allow for edits to be made during the meeting where changes were appropriate.

Members were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa referenced proposed section 1737 provides that proposed article 4.7 applies to the handling of hazardous drugs, including the standards established in USP 800. The language also provided a cross reference to other articles relating to nonsterile and sterile compounding. The cross references served as a reminder to licensees that where appropriate consideration of the other requirements may be appropriate depending on the activities being performed.

Title 16. Board of Pharmacy
Proposed Regulation

Proposal to Add Article 4.7 and add new titles and section 1737 – 1737.18 to Division 17 or Title 16 of the California Code of Regulations to read as follows:
Article 4.7 Hazardous Drugs

1737 Handling of Hazardous Drugs

In addition to the standards established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled *Hazardous Drugs – Handling in Healthcare Setting* shall meet the requirements of this Article.

A licensee performing non-sterile and sterile HD compounding shall comply with this article in addition to Article 4.5 and Article 4.6.

Members were provided an opportunity to comment; however, no comments were made.

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

Chairperson Serpa referenced section 1737.1 Introduction and Scope. Dr. Serpa provided the proposed language in this section established a requirement to ensure that as part of patient consultation information was provided concerning the handling and disposal of the hazardous drugs and related supplies furnished. Dr. Serpa believed the language presented in the materials was appropriate and consistent with the Board's consumer protection mandate.

1737.1 Introduction and Scope

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning on handling and disposal of an HD or related supplies furnished.

Members were provided an opportunity to comment; however, no comments were made.

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

Chairperson Serpa referenced section 1737.2 List of Hazardous Drugs. Dr. Serpa provided the section established requirements for assessment of risks consistent with the standards of the chapter. The draft language also established a requirement for a review of the facilities hazardous drug must be review and approved. Also, unlike the provisions in the other articles as proposed in this section the draft language specified that the designated representative was a single person approved by the pharmacist-in-charge (PIC). Dr. Serpa reviewed the language

and believed it was appropriate and consistent with the Board's consumer protection mandate.

1737.2 List of Hazardous Drugs
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) If an assessment of risk is performed as allowed in USP Chapter 800, it shall be performed or approved and documented at least every 12 months by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.

(b) The facility's list of HDs must be reviewed and approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.

(c) "Designated person" is a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

Members were provided an opportunity to comment.

Member Barker recommended adding an "s" to "Drug" in the title.

Members of the public were provided an opportunity to comment.

A representative of UCSD Health had a question about the assessment of risk as written in USP 800 was vague and asked how the Board plans to review the assessments of risk. The representative's understanding from the USP Committee that the alternative containment strategies were to be equivalent in minimizing exposure which could be subjective. Chairperson Serpa referred to the USP FAQs.

A pharmacist representative of Pacific Compounding Pharmacy recommended moving section (c) to (a) because it defines the designated person (DP). As the commentor understands the PIC couldn't be the DP and recommended clarifying the PIC could be the DP too.

A pharmacist Kaiser representative requested empirical data be presented for changes recommended and demonstrate the necessity to protect the public. The

representative stated the statement, "When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement." was not clear and requested clarification. The representative recommended the Board specify the nature of the record that was required to document the PIC's review of the practices that require the professional judgement of a pharmacist.

A commenter requested clarification if section (c) allowed for only one DP where USP allows for multiple DPs. Chairperson Serpa clarified this was the intent.

Chairperson Serpa indicated the renumbering of the section could be done offline with staff.

Members were provided to provide comment after public comment was received; however, no comments were made.

Chairperson Serpa referenced section 1737.3 Types of Exposure. Dr. Serpa provided the proposed language would require each entity to ensure that all employees were aware of the types of risks of exposure that may occur. Dr. Serpa agreed with the language and also suggested that an FAQ may be appropriate to include the various types of entities that could be covered.

1737.3 Types of Exposure
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Each entity shall ensure that all employees are aware of the types of risks of HD exposures that may occur as documented in the Chapter. This shall be documented in SOPs and training documents.

Members were provided an opportunity to comment.

Member Barker asked how entity was being defined for this regulation. Ms. Sodergren clarified the language was for many types of settings. Dr. Serpa noted it included those licensed by the Board.

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

Chairperson Serpa referenced section 1737.4 Responsibilities of Personnel Handling Hazardous Drugs. Dr. Serpa provided the proposed language would specify who was responsible for all of the activities and decisions made or approved by the designated person. This language ensured that the individual responsible for overall operational compliance has a clear understanding that their responsibility extends

to hazardous drug handling. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

1737.4 Responsibilities of Personnel Handling Hazardous Drugs
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The Pharmacist-in-charge, designated representative-in-charge, professional director, as applicable shall be responsible for all activities and decisions made or approved by the designated person.

Members were provided an opportunity to comment; however, no comments were made.

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

Chairperson Serpa referenced section 1737.5 Facilities and Engineering Controls. Dr. Serpa provided there were a number of requirements established in this section. Dr. Serpa noted that provisions were intended to reduce exposure risks, as an example section (a) requires the need to minimize traffic into the sterile compounding language. There were also provisions in (d) to require interlocking pass-through doors by January 1, 2026. This provides time for facilities to make changes to comply. Also, in (e) the proposed language included cross-reference to CETA Guidelines, similar to proposed regulation language for sterile compounding. Dr. Serpa believed the proposed language was appropriate and consistent with the Board's consumer protection mandate.

1737.5 Facilities and Engineering Controls
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) HDs used for nonsterile compounding shall not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

(b) When a containment primary engineering control (C-PECs), used for nonsterile and sterile HDs is placed in the same room, biannual certification must document that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.

(c) Handling volatile HDs:
(1) HEPA filters shall not be the only means of containment used.

(2) for sterile compounding, a biological-safety cabinet (BSC) as defined in USP Chapter 800 Class II Type A1 shall not be used.

(d) Where a pass-through is installed in a containment SEC the doors must be gasketed and interlocking. Effective January 1, 2026, all pass-through doors shall be a HEPA purge type pass-through vented to an unclassified space. A pass-through is not allowed between the containment SEC into an unclassified space.

(e) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.

(f) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.

(g) CSTDs shall be used when compounding antineoplastic HDs when the dosage form allows.

Members were provided the opportunity to comment.

Member Barker requested clarification on (c)(1) if the language should specify what shall be included rather than what shall not be included. Supervising Inspector Acosta advised the intent was to drive home what the chapter says is required. Dr. Serpa reminded participants the Board's regulations were on top of USP.

Member Barker ask for clarification about (d) to see if the two sentences could be combined. Dr. Serpa clarified in (d) there were three components adding that (1) and (3) could be combined but the (2) was a standalone. Dr. Serpa clarified the purge functionality was being added as a standard starting in 2026. Dr. Barker inquired if it applied to a containment SEC, the HEPA filter purge type. Dr. Serpa asked the Supervising Inspectors if language would need to be added to make it clearer that the Board is talking about the HEPA purge filter was only for devices covered under USP 800. Dr. Acosta suggested making (d) into two sections. Dr. Acosta inquired if in 2026 when all pass-through doors shall be HIPAA purge type pass throughs to an unclassified space. Dr. Acosta added by starting by saying containment SEC, it was clear it was for HD only. Dr. Acosta noted the regulations could be reviewed for continuity as was done for USP 795 and USP 797.

Members of the public were provided the opportunity to comment.

A compounding pharmacist commented on (e) as being outdated and not providing location or placement. The compounding pharmacist commented on (g) that "shall" instead of "should" was too strong language.

A pharmacist representative of Sutter Health commented on (c) about the term "handling" as it was already defined in USP and proposed to specified clarification. The pharmacist representative commented on section (f) if an FAQ could provide an example.

A pharmacist representative of Kaiser commented on (a) the requirement around storage of HD used for non-sterile compounding and not storing those in areas designated for sterile compounding. The representative noted that there were some facilities that may infrequently compound non-sterile HD drugs on occasion and didn't agree with the requirement for those who do it on occasion. The representative commented about (c) with a concern about for inspection purposes with the term "volatile" and requested clarification. The representative commented on (d) noting concern that the requirement of a pass through not go from C-SEC to classified space could result in reduce access to public.

A representative from UCSD Health requested clarification about the pass through effective 1/1/26. Dr. Serpa clarified and updated the language so that after 1/1/26 all pass through doors shall be a HEPA purge pass through.

Chairperson Serpa summarized the changes discussed and requested: suggesting that (d) be divided into two sections; changing the word "handling" in (c); suggesting FAQ for (f); and suggesting more discussion on (a) as for environmental and personal safety, it was better to have the non-sterile and sterile be separated.

Member Barker noted it was worth discussing again because if not to be stored in a sterile compounding area but bringing supplies into the area, SOPs would apply. Dr. Barker added it could be tested during environmental testing and understood it creates a hard situation to store a small amount of drugs in the new space. Ms. Sodergren suggested adding to (a) "contamination and" as well as "except as defined in the SOPs."

Chairperson Serpa referenced section 1737.6 Environmental Quality and Control. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The proposed language specified requirements for the standard operation procedures to establish provisions for environmental wipe sampling and clarified the proposed language included the minimum actions that number be taken when actionable contamination is found.

1737.6 Environmental Quality and Control

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.
(a) An entity's SOPs shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.
(b)When actionable contamination is found, at minimum the following shall occur:
(1) Reevaluate work practices
(2) Reevaluate the appropriateness of deactivation, decontamination and cleaning agents
(3) Re-train personnel on deactivation, decontamination and cleaning
(4) Re-train personnel on donning and doffing appropriate PPEs

Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment.

A pharmacist representative from Kaiser commented on (a) and (b) reading as a facility selecting the frequency including not doing the wipe sampling at all. The representative asked if that was the case, the regulation believed the appropriate level of flexibility was allowed to determine the frequency and nature of wipe sampling to be perform. Specifically, on (b), proposed text read "when actionable contamination is found" and suggested modifying to say "when contamination that exceeds the level specified in the entity's SOP is found" to be clearer. Dr. Serpa asked Dr. Kalantar if a frequency of none was allowable. Dr. Kalantar commented a frequency was required.

A compounding pharmacist added USP 800 requires every six months sampling but recommended USP 800 to stand on its own in terms of wipe sampling and requested evidence.

Chairperson Serpa addressed the request for (b) to harmonize with "actionable" in USP 797.

The Committee took a break from 10:53 a.m. to 11:05 a.m. Chairperson Serpa took roll call after the break. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensing Member. A quorum was established.

Chairperson Serpa referred to section 1737.7 Personal Protective Equipment (PPE). Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted the use of PPE was

extremely important in protecting staff and there were many provisions in this section that were permissive in Chapter 800 that the proposed language will make as requirements. Dr. Serpa provided as an example (d) makes requirements specifically related the removing of PPE. The proposed language in this subsection provides specific information that PPE worn during compounding must be disposed of in a proper waste container while also establishing that the SOPs must describe where donning and doffing can occur.

1737.7 Personal Protective Equipment (PPE)

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Two pairs of gloves labeled to meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.

(b) The outer pair of gloves labeled to meet the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile compounding both pairs of gloves labeled to meet the ASTM D-6978 standard chemotherapy gloves shall be sterile.

(c) Outer gloves used for compounding must be changed between each different type of HD preparation and the standards established in Chapter 800 if continuously compounding a single HD preparation. The facilities SOPs shall define the circumstances under which the gowning and gloves must be changed between HD handling/preparations.

(d) PPE shall be removed cautiously to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPS must be in place which describe in detail the donning and doffing of PPE and where it takes place in the C-SEC.

(e) An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:

(1) Attending to HD spills larger than what can be contained with a spill kit
(2) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
(3) There is a known or suspected airborne exposure to powders or vapors.

Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment.

A compounding pharmacist representative of Pacific Compounding Pharmacy requested removing "labeled" and change to "two pairs of gloves that meet the ASTM d697 etc. standard" noting meeting the standard was appropriate but not all gloves that meet the standard actually pay to have the labeling. The commenter requested better defining "type."

A pharmacist representative of Kaiser agreed with the prior comment regarding the gloves in (a). The representative commented on (c) to clarify "type" or delete requirement. The representative commented on (d) that "removed cautiously" was a non-specific and subjective term that could lead to unequal application during inspection. The representative commented on (e) (2) requesting data substantiating requirement change and if no data exists, the requirement be removed.

A pharmacist representative of Sutter Health agreed with the Kaiser representative on (e)(2).

The Committee discussed removing the word "labeled" and replace with "meet" but noted the documentation to meet the requirement would need to be stored. Dr. Serpa indicated the language would be refined.

The Committee discussed the change to "type" meaning no cross contamination between two products. The intent was to have no cross contamination of one chemotherapy onto the next product and cross contamination could be on the outside of the container. Dr. Acosta confirmed the intent was the type of HD to ensure no cross contamination. The Committee agreed an FAQ would be helpful.

Chairperson Serpa was concerned with changing (e)(2) as the employee needs to be protected. Dr. Acosta confirmed the language was to take USP language and change "should" to "shall."

Chairperson Serpa referenced section 1737.8 Hazard Communication Program. Dr. Serpa provided the proposed language required that the designated person was required to develop the entity's communication plan. Dr. Serpa believed this was appropriate and consistent with the Board's mandate.

1737.8 Hazard Communication Program
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The designated person is responsible for developing the entity's hazardous communication program. The program shall be documented in SOPs and training documents.

Members were provided an opportunity to comment.

Member Barker commented on the entity's hazardous communication program that in larger facilities the overarching was usually the environmental health and safety which isn't always the standard. Dr. Barker wondered how the hazardous communication program required by Title XIII CCR General Industry Safety Orders section 5194; Health and Safety Code (HSC) sections 25500 and 25520; and Department of Toxics Substances Control could be harmonized to reduce duplicative efforts.

Chairperson Serpa understood in larger organizations it was usually a team rather than a person and the intent was for the designated person that they be part of the development of the hazardous communication plan.

Member Barker suggested in changing to "developing or participating in the development of the entity's" as well as cross reference other CA law sections (e.g., CalOSHA, etc.).

Members of the public were provided an opportunity to comment.

A pharmacist representative of Kaiser appreciated the discussion and comments from Dr. Barker that in larger entities there are other groups involved.

A pharmacist representative of Sutter Health had similar concern with Dr. Barker's and agreed with the proposed change as well as recommended to include the single designated person is responsible for participating in development or being responsible for what the pharmacy compounding chemicals and hazards are in the pharmacy rather than the broader OSHA communication plan which is a broader team.

Chairperson Serpa referenced section 1737.9 Personnel Training. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The proposed language specified the training requirements and included a cross reference to the documentation portion of the article. The language includes that personnel that fail any aspect of training will be required to successfully pass reevaluation in deficient areas before being involved in handling of hazardous drugs. Dr. Serpa noted language was added to those only who have direct oversight over personnel and HD compounding up to 14-days to pass re-evaluation of deficient areas as a result of public comment.

Members were provided the opportunity to comment; however, no comments were made.

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

Chairperson Serpa referenced section 1737.10 Receiving. Dr. Serpa advised the proposed language in subsection (a) was included as the requirements were necessary to avoid contamination in the event of the spill during the shipping and receiving of an API adding the package needs to be appropriately identifiable as a hazardous product.

1737.10 Receiving
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

All HD API and antineoplastic HD shall be received from the supplier in segregated impervious plastic and labeled as HD on the outside of the delivery container.

Members were provided the opportunity to comment.

Member Barker noted the proposed language stated, "shall be received from the supplier" but added FAQ 57 states suppliers aren't required to ship in impervious plastic" and wasn't under the control of the receiver. Dr. Serpa added the Board had control over wholesalers shipping in the state. Dr. Kalantar agreed this was for the wholesalers to follow in regulation. Dr. Acosta suggested changing the verbiage to "HD shall be shipped" to place the burden on the shipper.

Members of the public were provided the opportunity to comment.

The Committee heard comments from representatives of Kaiser, Pacific Compounding Pharmacy, CSHP, and Sutter Health agreeing the onus should be on the shipper as the receiver cannot guarantee how the materials will be received.

Chairperson Serpa noted wholesalers were also receivers as well as shippers as mentioned by the CSHP representative.

Chairperson Serpa referenced section 1737.11 Labeling, Packing, Transport and Disposal. Dr. Serpa provided the proposed language was incorporating the labeling requirements contained in other sections of pharmacy law to serve as a reminder of the labeling requirements that must be met. Additionally, subsection (b) clarified that the package must be labeled as a hazardous drug on the outside

packaging. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

1737.11 Labeling, Packing, Transport and Disposal
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

(b) All HD API and antineoplastic HDs shall be transported in impervious plastic container and labeled as HD on the outside of the container.

Members were provided the opportunity comment.

Member Barker recommended changing (b) to "in an impervious" to correct the grammar.

Dr. Kalantar suggested changing the title to "Packaging" instead of "Packing."

Members of the public were provided the opportunity comment; however, no comments were made.

Chairperson Serpa referenced section 1737.12 Dispensing Final Dosage Form. Dr. Serpa provided the proposed language specified that equipment used must be decontaminated after each use. Dr. Serpa noted this was another example where the chapter included this concept as permissive. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

1737.12 Dispensing Final Dosage Form

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Equipment used in nonsterile compounding shall be dedicated for use with HDs and shall be decontaminated after each use.

Members were provided the opportunity to comment; however, no comments were made.

A compounding pharmacist representative of Pacific Compounding Pharmacy commented with regards to the cleaning there were many pieces of equipment

that do not come in contact with the HD or APIs (e.g., pieces of the electronic mortar and pestle). The representative recommended leaving this up to the SOPs.

Chairperson Serpa referenced section 1737.13 Compounding. Dr. Serpa noted the the language in this section made permissive standards within the Chapter, requirements in the proposed regulation language. Dr. Serpa believed it to be appropriate.

1737.13 Compounding
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) A preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each type of HD and at the end of daily compounding activity.

(b) Only one HD drug may be handled in a C-PEC at one time if making multiple preparations.

Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment.

A pharmacist representative of Sutter Health regarding (a) requesting not using preparation mats as they have found that the use of the mats does not facilitate good decontamination processes of wiping vials or the direct compounding surface and being able to remove gloves/mats during each compound. The representative noted the burden was in some facilities where they could be using a hundred mats or more a day as batches can't always be done due to scheduling. The representative encouraged the use of the preparation mat around spill and to utilize cleaning processes in the direct compounding area routinely so that an organization can assess for use and not be a requirement.

A compounding pharmacist representative from Pacific Compounding Pharmacy commented in agreement with the Sutter Health representative. The representative added if you have to change a mat with every chemo, it would an opportunity for create more hands going in and out of hood noting the SOPs should be appropriate. The representative commented on (b) requesting removal of "if making multiple preparations."

A pharmacist representative from Kaiser commented in agreement with the Sutter Health and Pacific Compounding Pharmacy representatives and agreed with not having to use the preparation mat. The representative was not aware of evidence that indicated the use of the preparation mats and the compounding of hazardous drugs enhancing patient safety resulting but increase in waste and would result in an increase of cost of care. The representative added with regard to (b) that many modern chemo treatment plans include multiple agents that are administered on the same treatment day and believed that establishing a requirement that only one HD drug may be handled in the PEC at a time if making multiple preparations will be at tension with the nature of modern chemotherapy regimens and requested empirical data be provided.

Chairperson Serpa clarified the word "disposable" needed to be added for preparation mats. Dr. Serpa posed the question to the Committee when it should be required and believed it was important to use in the non-sterile environment.

Member Barker shared having experience using mats but shared a concern about supply issues. Dr. Barker supported the use of the mats but had concerns with the sterility on top of the mat noting that the sterility and HD management could be at odds.

Chairperson Serpa thought adding the word "disposable" would help to clarify that a reusable mat couldn't be used. Dr. Serpa agreed with harmonizing (a) with the types of HD drugs used to make it clear. Dr. Serpa explained (b) was written to avoid the unintended consequence of one dose at a time. Dr. Barker indicated it could be made clearer and included in an FAQ.

Chairperson Serpa referenced section 1737.14 Administering. Dr. Serpa noted the proposed language in this section was ensuring that the hazardous drug was placed in an appropriate container and labeled as hazardous. Further, it ensures that patients and/or their agents will have the appropriate gloves to protect themselves when handling the hazardous drug. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

1737.14 Administering

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) When dispensing an HD to a patient or caregiver for administration, the pharmacy shall attach and prime all tubing, attach a CSTD when appropriate, and place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container.

(b) There shall be a sufficient supply of gloves to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the

patient's agent when dispensing an antineoplastic HD. The gloves shall meet the ASTM D-6978 standard.

Members were provided the opportunity to comment.

Member Barker indicated it might be difficult to control the supply.

Chairperson Serpa understood but noted USP 800 indicates the entity has greater roles and responsibilities so that part of the hazardous communication team would be involved with ensuring there were adequate waste streams that have adequate gowns and linens to protect the staff.

Members of the public were provided the opportunity to comment.

A compounding pharmacist representative of Pacific Compounding Pharmacy commented regarding (a) if a new container would have to decontaminate a new container and requested "cleaned or" be added before "decontaminated." For (b) the representative inquired who determines "sufficient supply" and requested the first sentence to be amended to say, "There shall be a blank supply of ASTM standard meeting gloves" to clarify.

A pharmacist representative of Sutter Health commented on concern with the term "sufficient" supply of ASTM gloves. The representative asked how it would be enforceable and how they should prepare in order to be compliant in alternative settings (e.g., home health, etc.).

A commenter suggested adding "antineoplastic" before "HD" in (a).

Chairperson Serpa confirmed with Dr. Kalantar the intent would be antineoplastic HDs.

The Committee took a break from 12:07 p.m. to 12:50 p.m. Chairperson Serpa took roll call after the break. Members present included: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensing Member. A quorum was established.

Chairperson Serpa referenced section 1737.15 Deactivation, Decontamination, Cleaning and Disinfecting. Dr. Serpa noted the proposed language in this section was explicitly stating that agents used must be used in accordance with manufacturer's specification. Dr. Serpa recalled this was similar to language in other articles previously considered. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. Dr. Serpa noted included were concepts contained with the Chapter that were

currently permissive but the proposed language would make requirements to protect patients and personnel. Dr. Serpa believed the language was appropriate and consistent with the Board's mandate.

1737.15 Deactivation, Decontamination, Cleaning, and Disinfecting
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.
(a) Deactivating, decontaminating, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications and shall be surface compatible.

(b) Agents used for deactivation, decontamination, cleaning and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with appropriate solution and shall not delivered by a spray bottle to avoid spreading HD residue.

(c) SOPs for decontamination and deactivation procedures for the final HD product shall be created by the entity in accordance with the entity's SOPs and approved by the pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable.

Members were provided the opportunity to comment.

Member Barker commented that the USP language requiring wipes only was limiting.

Members of the public were provided the opportunity to comment.

A compounding pharmacist representative of Pacific Compounding Pharmacy commented with concern for (c) with decontaminating deactivating procedures for a final HD product. The representative was not aware if the IV bag was of appropriate material to handle decontamination or deactivation agents without causing problem to the preparation. The representative was also not comfortable working with tubing lines and wiping down, etc. The term "deactivate" was noted as a scientifically imprecise phase.

A pharmacist representative of Sutter Health commented in agreement with Dr. Barker's comments about the wipes and noted (c) was a hard bar to make a must. The final HD product versus preparation was pointed out as a difference in wording.

Chairperson Serpa referred to section 1737.16 Spill Control. Dr. Serpa noted the proposed language in this section was again requiring the entity to address specific items within their SOPs. Dr. Serpa advised the approach ensured an entity has considered the issue and developed the process to protect employees. Dr. Serpa

believed the language as presented is appropriate and consistent with the Board's consumer protection mandate.

1737.16 Spill Control
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) The entity shall have an SOP addressing the use of appropriate full-facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

(b) The entity shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how a qualified personal will be available at all times while HDs are handled.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment.

A pharmacist representative of Sutter Health commented in section 1736.7 (a) talked about the use of a full-face piece chemical cartridge type respirator but didn't mention any other type of respirator that could be used and wondered why PAPRS or other type of vapor exposure respirators were allowed. The representative noted as in previous sections, it would be helpful to reference the type of respirator that was potential to the exposure.

Dr. Serpa commented they will look to harmonize about respirators in other sections.

Chairperson Serpa referenced section 1737.17 Documentation and Standard Operating Procedures. Dr. Serpa noted the proposed language in this section explicitly stated that the entity shall follow their SOPs. The proposed language also required SOPs in 16 areas. The identified areas were permissive concepts in the Chapter. Dr. Serpa clarified in the interest of safety, the proposed language was requiring the SOPs to address each of these areas. The proposed language included a requirement for SOPs to be reviewed at least every 12 months and specified that changes in SOPs must be disseminated in writing to appropriate staff prior to implementation. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate.

1737.17 Documentation and Standard Operating Procedures
The requirements of this section apply to the handling of HDs in addition to the

standards in USP Chapter 800.

(a) Any entity engaged in the compounding or handling of HDs shall maintain and follow written SOPs.

(b) The SOPs for compounding or handling HDs shall include at least the following:

(1) Hazard communication program
(2) Occupational safety program
(3) Designation of HD areas
(4) Receipt
(5) Storage
(6) Compounding, if applicable
(7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable
(8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal), if applicable
(9) Deactivation, decontamination, cleaning, and disinfection
(10) Dispensing, if applicable
(11) Transport
(12) Administering, if applicable
(13) Environmental monitoring (e.g., wipe sampling)
(14) Disposal
(15) Spill control
(16) Medical surveillance

(c) The pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable, shall work with the entity's designated person to ensure HD handling SOPs are reviewed at least every 12 months and this review is documented.

(d) SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated in writing to the staff responsible for handling HDs prior to implementation. All notifications of such changes and the changes shall be documented in SOPs and training documents.

(e) Failure to follow written SOPs shall constitute a basis for enforcement action.

Members were provided the opportunity to comment.

Member Barker asked if "providing in writing" would allow electronic versions. Ms. Sodergren provided if the intent was to be written or electronic communication but not orally or verbal communication but could work with counsel on the language.

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

Chairperson Serpa referenced to the final section 1737.18 Medical Surveillance. Dr. Serpa believed the language as presented was appropriate and consistent with the Board's consumer protection mandate. The Chapter included this concept as permissive. Dr. Serpa agreed it should be a requirement to protect employees handling hazardous drugs and believed the proposed language was appropriate.

1737.18 Medical Surveillance

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Elements of a medical surveillance program shall be consistent with the entity's Human Resource policies and employees handling HDs must be aware of the program.

Members were provided the opportunity to comment; however, no comments were made.

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

Chairperson Serpa thanked participants for the discussion. Dr. Serpa stated in addition to changes discussed with the Committee's agreement, Dr. Serpa would work with staff to finalize language. Similar to the regulation text considered in prior meetings, the Committee will work to ensure consistency between these proposed requirements and those in the proposed requirements for the compounding of nonsterile and preparations and radiopharmaceuticals where appropriate. These changes would be completed prior to the Board's consideration of all of proposed regulations during the April 2023 Board Meeting.

Chairperson Serpa thanked Supervising Inspectors Acosta, Kalantar, and Panella-Spangler who dedicated significant time preparing for and attending the meetings, providing education us on the USP Chapters and working very diligently to develop the regulation text considered during the meetings. Dr. Serpa noted the Board was extremely fortunate to have subject matter experts that were truly committed to consumer protection.

Chairperson Serpa thanked all of the stakeholders that attended and participated in the process noting it was vital to ensure that all aspects of an issue as part of the decision-making process were considered.

Chairperson Serpa looked forward to the discussion at the Board Meeting and hoped the Board would be in a position to move regulation text to initiate the formal rulemaking process as November 1, 2023, was around the corner and licensees benefit greatly from clarity to understand requirements.

VII. Discussion and Consideration of Proposal to Amend Title 16, California Code of Regulations Sections Related to Compounding of Nonsterile and Sterile Preparations for Dispensing by Veterinarians for Animal Patients

Chairperson Serpa recalled at the February 2023 discussion on requirements for nonsterile compounding, the Committee received public comment regarding compounding for animal patients and a request to expand current provisions. During the discussion at that time, the Committee determined it appropriate to leave the language as it was currently provided in the law which specified that a pharmacy may compound a reasonable quantity sufficient for administration or application to a patient solely in prescriber's office or furnishing of not more than a 120-hour supply for veterinary medical practices.

Chairperson Serpa advised subsequent to that discussion, the Committee received further comments from the California Veterinary Medical Association (CVMA) requesting reconsideration. Dr. Serpa noted a copy of the letter was included in the meeting materials. Dr. Serpa believed it was possible to extend the provisions for non-sterile preparations to a seven-day supply after reviewing the letter and having an opportunity to confer with staff and receive information from the Board's expert on veterinary compounding. Dr. Serpa believed the Board could establish provisions to allow for a 28-day supply for sterile ophthalmic preparations under specified conditions, including a requirement that such sterile preparations meet the requirements of USP Chapter 797 Section 14.5.

Chairperson Serpa added the area of veterinary compounding was challenging because the requirements vary from human compounding under federal law. In additional there were many national manufacturing drug shortages. Dr. Serpa added many of the drugs listed in the comment letter that were found to be difficult to obtain were not compounded drugs but as a result of the national manufacturing shortages. Dr. Serpa believed the comment letter highlighted the need for additional education in this area where perhaps the use of compounded products was contrary to federal law.

Chairperson Serpa noted the meeting materials included the two areas where believed it may be appropriate to update language. Dr. Serpa added if there was agreement with the Committee, Dr. Serpa would work with staff the draft language to incorporate the changes for the Board to consider the language at the April 2023 Board Meeting.

Members were provided the opportunity to comment.

President Oh and Member Barker spoke in support of the proposed changes to pharmacy services to veterinarians.

Members of the public were provided the opportunity to comment.

A representative of CVMA commented in disagreement with the statement about drug products but CVMA supported the recommended changes and appreciated the Committee's consideration of the comment letter in making the recommendations.

A pharmacist representative of Pacific Compounding Pharmacy commented in support.

VIII. Discussion and Consideration of Draft Statutory Proposal to Amend Business and Professions Code Sections 4081 and 4105

Chairperson Serpa recalled at the January 2023 Meeting, the Committee considered a recommendation from staff to amended Business and Professions Code sections 4081 and 4105 to address challenges staff were experiencing in obtaining records necessary to evaluate pharmacy operations for compliance with Pharmacy Law. During prior discussions, the Committee requested staff develop statutory language for consideration. The meeting materials included the draft language. Dr. Serpa reviewed the language and believed the language was appropriate. If the Committee similarly agreed, Dr. Serpa believed the Committee could offer a recommendation to the Board for consideration at the April 2023 Board Meeting..

Members were provided the opportunity to comment.

President Oh asked for the reason for the strike out in BPC section 4105 (a). Ms. Sodergren clarified the language was updated to reflect as required by the chapters. Dr. Oh requested the acquisition and disposition of dangerous drugs and dangerous devices be added to the meeting materials so that it was covered.

Motion: Sponsor statutory language as presented.

Proposal to Amend Business and Professions Code section 4081
(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every

manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

(e) In addition to the records described in subdivision (a) records that must be maintained include staffing schedules, pharmacy personnel job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations.

Proposal to amend BPC 4105

(a) All records or other documentation required by this Chapter ~~of the acquisition and disposition of dangerous drugs and dangerous devices~~ to be maintained by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

M/S: Oh/Barker

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

A pharmacist representative of Kaiser recommended allowing for records to be maintained solely in an electronic format regardless of the format they were made if maintained consistent with provisions of the BPC section 470(c) and California Evidence Code sections 1550 and 1552 to help facilities struggling to maintain records in paper format that may otherwise be able to be maintained in a non-alterable electronic format.

President Oh requested incorporating the comment if allowable. Ms. Sodergren requested discussing with the AG's Office before incorporating the change. Dr. Oh kept the motion as stated and requested it to be discussed at the April 2023 Board Meeting.

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

Committee Member	**Vote**
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support

IX. Review and Discussion of Enforcement Statistics

Chairperson Serpa referred to the enforcement statistics included in the meeting materials. The Board initiated 2,686 investigations and closed 2,376 investigations. Outcomes varied and included the issuance of 141 letters of admonishment, 766 citations and referral of 181 cases to the AG's Office. Dr. Serpa highlighted the last statistic of 181 cases have been referred to the AG's Office. Dr. Serpa believed there was a misconception about the Board's disciplinary activities with some suggesting that the Board is always seeking to discipline a license. The data tells otherwise as referrals to the AG's Office was about 7.6 percent.

Chairperson Serpa highlighted that the Board secured six interim suspension orders and has been granted eight Penal Code 23 restrictions. In both instances the Board was successful in securing immediate public protection through these actions while the disciplinary case process continues. Such actions were core to the Board's mandate. Investigation timeframes were also included. Dr. Serpa thanked Supervising Inspectors who have worked to reduce supervisor review time with two vacancies. Dr. Serpa noted it was commendable and appreciated. Dr. Serpa reminded Members at the July 2023 meeting, the Committee will receive a three-year comparison data to help evaluate trends.

Chairperson Serpa asked about the statistics for awaiting final closure where the April 2023 showed the average days going up to 75 days which wasn't consistent with the previous reports. Ms. Sodergren provided staff was looking into the data as one identified bottleneck and continue to validate and provide updates at the April 2023 Board Meeting.

Members were provided the opportunity to comment; however, no comments were made.

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

X. Future Committee Meeting Dates

Chairperson Serpa reminded the next meeting was scheduled July 18, 2023. Dr. Serpa advised the meeting will be held in person with the option for members of the public to participate via WebEx.

XI. Adjournment

Chairperson Serpa and President Oh thanked all participants. The meeting adjourned at 1:25 p.m.