California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

California State Board of Pharmacy
Department of Consumer Affairs
Enforcement and Compounding Committee Meeting Minutes

Date: January 23, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive, First Floor Hearing Room
Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM REMOTE LOCATIONS VIA WEBEX

Board Members Present:
Maria Serpa, PharmD, Licensee Member, Chair
Renee Barker, PharmD, Licensee Member, Vice Chair
Indira Cameron-Banks, Public Member
Seung Oh, PharmD, Licensee Member
Nicole Thibeau, PharmD, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel
Debbie Damoth, Executive Specialist Manager

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

Chairperson Serpa called the meeting to order at approximately 9:01 a.m. As part of the opening announcements, Chairperson Serpa reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee 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 in Sacramento were provided the opportunity to comment.

A representative from Pharmapod requested the opportunity to present their platform to the Committee at a future meeting.

Members of the public were provided the opportunity to comment via WebEx.

A representative of Sutter Health requested that the Committee provide an article in *The Script* or a list of frequently asked questions (FAQs) regarding compounding standards. The representative stated there was confusion based on the statement on the Board's website if facilities could move forward fully with USP standards or if facilities must also abide by the current California regulations.

A representative from the PSO Alliance for the Patient Medication Safety requested to make a presentation to the Board at a later date.

A consulting pharmacist with ambulatory surgery centers asked about the Board's involvement with ambulatory surgery centers, noting issues that have been seen related to controlled substance storage, management, and records. The consulting pharmacist asked if there was a possibility of the Board to regulate the environment and asked the Board for assistance, noting it was a large issue.

Chairperson Serpa encouraged the consulting pharmacist to use the Ask an Inspector service provided by the Board of Pharmacy.

A pharmacist was following up on a request they made at the last full Board meeting for FAQs regarding adding flavoring agents. The pharmacist requested that this be added as a future agenda item. The pharmacist asked the Board keep in mind California specific laws, particularly Business and Professions Code (BPC) section 4052.5, which allows the pharmacist to make changes in the form of the medication without necessarily contacting the prescriber. Dr. Serpa directed the pharmacist to the Board's alerts sent out to answer the question.

Chairperson Serpa noted many comments received were for current agenda topics. Dr. Serpa added there were also members of the public interested in the contracting process for the entity for medication errors that would also be discussed in a future agenda item.

Members were provided the opportunity to add agenda items to a future agenda.

Member Thibeau expressed interest in hearing presentations from commenters about the entity for medication errors or to make sure they have the opportunity to be a part of the process. Dr. Serpa noted the contracting process would be discussed later on the agenda.

III. Discussion, Consideration, and Approval of Draft Minutes from the October 19, 2023 Enforcement and Compounding Committee Meeting

The October 19, 2023 Enforcement and Compounding Committee meeting minutes were presented for review and approval.

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

Motion: Approve the October 19, 2023 Enforcement and Compounding Committee meeting minutes as presented.

M/S: Oh/Barker

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

IV. Presentation on the Canadian Medication Incident Reporting and Prevention System (CMIRPS) by ISMP Canada.

Chairperson Serpa recalled during the October 2023 meeting as part of the Committee's implementation discussion for Assembly Bill 1286, the Committee decided it was appropriate to receive presentations from entities that currently receive and review medication errors. Dr. Serpa introduced and welcome Enna Aujla, Sylvia Hyland, Melissa Sheldrick, and Carolyn Hoffman from ISMP Canada.

Ms. Hoffman introduced her team. Ms. Sheldrick shared how medication errors impacted her life by the death of her young son due to medication errors. Ms. Hoffman reviewed the medication incidents and ISMP Canada's Unique Mandate. Ms. Hyland presented on the reporting, learning, and acting on medication incidents. Ms. Sheldrick discussed how each pharmacy contributes their incident data. Ms. Aujla presented provincial and national shared learning improvements. Ms. Hoffman, Ms. Aujla, Ms. Sheldrick, and Ms. Hyland continued with explaining data analysis and shared learning practice supports with ISMP Canada.

Members were provided the opportunity to comment.

Member Barker asked about the need to increase diversity and inclusivity in its activities. Ms. Sheldrick provided an update on the processes being updated to address increased diversity and inclusivity for all Canadians.

President Oh thanked ISMP Canada representatives for their time.

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

Members of the public were provided the opportunity to comment via WebEx.

A representative of CCAP asked what the fees were for processing. Ms. Aujla provided the annual cost of $70 plus tax and another fee to the platform provider specific to the platform provider.

A pharmacist asked if there were other reporting programs in Canada. Ms. Hoffman provided there were other programs based on facility type. Ms. Sheldrick added consumers also provide reports on errors.

A pharmacist commented about a concern regarding access to the error reporting database (*e.g.*, by media, attorneys, etc.) and asked about the protection of the data as a way of encouraging reporting of the data. Ms. Hoffman provided that the error reporting information submitted was anonymous and not patient/case specific. Ms. Hoffman noted there were clear policies and procedures in place to protect privacy as well as data sharing agreements. Ms. Hoffman noted that this had never been an issue. Ms. Hyland confirmed the data is anonymous and de-identified. Ms. Hoffman noted the different types of legal systems in Canada and the United States.

Members were provided the opportunity to comment after public comment was received. However, no comments were made.

Chairperson Serpa thanked the ISMP Canada representatives for their presentation and time.

V. Presentation on Medication Error Reporting by the Agency for Healthcare Research and Quality

Chairperson Serpa advised the Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency charged with improving the safety and quality of healthcare nationally. The agency manages the Network of Patient Safety Databases (NPSD) that contains information voluntarily submitted by patient safety organizations.

Chairperson Serpa welcomed and introduced Andrea Timaskenka, Director of the Patient Safety Organization Division at the US Department of Health and Human Services, to provide a presentation to the Board on the development of the NPSD.

Ms. Timaskenka reviewed the most relevant authorities for the PSO program including the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and originating idea of the PSQIA legislation. Ms. Timaskenka explained PSQIA as a national learning system.

Ms. Timaskenka described the functions of the AHRQ's PSO Programs including the implementation of PSQIA and the legal protections included under the PSQIA as well as what was not protected under the PSQIA. She further explained who works with PSOs and the value added when hospitals work with PSOs. Ms. Timaskenka reviewed common formats used in multiple types of facilities.

Ms. Timaskenka also reviewed the national data systems related to the PSO programs, NPSD, and NPSD dashboards.

Members were provided the opportunity to comment.

President Oh thanked Ms. Timaskenka for her presentation and time.

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

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

The Committee took a break from 10:43 a.m. to 11:00 a.m. After break, roll call was taken. The following members were present via WebEx: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

VI. Presentation on the State Contracting Process by the California Department of Consumer Affairs

Chairperson Serpa advised the Board received requests from a number of entities interested in serving as the entity to receive medication error reports under new BPC section 4113.1. Dr. Serpa provided a representative from the Department of Consumer Affairs would provide an overview of the request for proposal process for interested entities to understand the process. Dr. Serpa believed the presentation would also help inform the Committee about necessary information that will be required by the Board as part of the process. Dr. Serpa welcomed and introduced Miriam Lopez, Staff Services Manager II, from the Department of Consumer Affairs Business Services Office.

Ms. Lopez provided an overview of the Request for Proposal (RFP) process together with the six phases of the process including the request, RFP review, advertisement period, RFP evaluation/award, contract preparation and approvals, and contract distribution.

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

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

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

VII. Discussion and Consideration of Scope of Work and Contract Requirements for Inclusion in the Invitation for Bid for Interested Parties Seeking to Serve as the Approved Entity under Business and Professions Code Section 4113.1

Chairperson Serpa provided the Committee would now review policy questions to assist in the discussion on contract requirements.

1. **Does the Committee wish to provide feedback on the required elements of the medication error reports? Board staff recommend that at a minimum the following elements be included in error reporting.**[1]
    a. **Pharmacy Unique Identifier (Unique Identifier to be established by the contracted vendor)**
    b. **Type of Pharmacy (drop down menu)**
    c. **Date of incident**
    d. **Type of event (drop down menu)**
    e. **Stage of process where error occurred (drop down menu)**
    f. **Type of patient (drop down menu)**
    g. **Age of patient (drop down menu)**
    h. **Sex**
    i. **Patient harm (drop down menu)**
    j. **Type of staff involved (drop down menu, may select more than one)**
    k. **Staffing at the time the event occurred or on the date the incident occurred**
    l. **Volume of work on the date of the incident (fill-in specified number, *e.g.*, number of new prescriptions, number of refill prescriptions, number of vaccines administered, etc.)**
    m. **Was technology involved (yes/no, if yes, brief description)**
    n. **Medication involved (narrative, drug name, strength and quantity prescribed)**
    o. **Prescription Details (*e.g.*, e-prescribed, faxed, written, transferred, etc. (drop down menu)**

[1] Staff note that the community pharmacy common format established by AHRQ provides the foundation for many of the recommendations offered.

p. Prescriber type (drop down menu)
q. Contributing factors (narrative)
r. Report date

Dr. Serpa explained the first policy question for consideration was to provide feedback on the staff's recommendations for required elements of the medication error reports. Dr. Serpa noted that the staff recommendations were similar to the elements included in the common format used by AHRQ's Network of Patient Safety Databases and that she was comfortable with the recommended elements. Dr. Serpa believed the recommended elements would provide a framework to allow for the Board to gain insight into the frequency and types of medication errors and contributing factors.

Members were provided the opportunity to comment.

Member Thibeau asked what element "F" labeled as "Type of patient" means. Dr. Thibeau also asked if element "H" labeled as "Sex" meant sex assigned at birth or gender identity, noting they should be separated if required but was not sure if they were relevant.

Dr. Serpa noted element "H" was not a drop-down menu so that it wouldn't appear to be limited. Dr. Serpa added there were some medications provided to pregnant women that maybe useful data points but would be interested to know the best method to collect the information. Ms. Sodergren thought they were data points to provide additional context to the error but could reach out to AHRQ for clarification. Dr. Thibeau agreed it would be important to know for a person of childbearing potential; a transman who was pregnant; or if testosterone dose was received for a transgender medicine versus a cisgender male receiving testosterone.

Member Barker agreed with Dr. Thibeau about element "H." Dr. Barker added the error reporting system used at her workplace had more patient identifiers which might be helpful (*e.g.*, race, culture, ethnicity, spoken language, ethnic background, written language, language barriers, etc.) to capture who was experiencing the errors. Dr. Barker commented on element "M" regarding "Was technology involved (Yes/No, if yes, brief description)" asking if there could be a drop-down menu as there were many sources of technology used that could be the source of an error.

Member Oh commented about elements "H" and "M" noting for technology a description could be added and more drop-down options (e.g., ADDS, counting machine, etc.).

Dr. Serpa expressed concern about the required elements being in place for many years based on the contracting process and requested if drop-down menus were added, a field for "other" could be included. Dr. Serpa asked if "gender" was more appropriate than "sex" but was not sure which term was appropriate. Dr. Serpa agreed with the concept of adding language barriers.

Dr. Barker thought for element "M" there could be categories listed (*e.g.*, IV workflow manager, ADDS, etc.). Dr. Serpa would work with staff to bring something to the Board meeting that would be a little more descriptive. Dr. Thibeau agreed with collecting data on race and ethnicity to look for discrepancies and see if implicit bias was part of the medication error.

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

Members of the public were provided the opportunity to comment via WebEx.

A medication safety officer agreed with the discussion by the Committee on the elements on sex, gender, and technology.

A pharmacist manager for the Walgreens Pharmacy Affairs team commented Walgreens already participates in PSOs who are listed by AHRQ. The PSOs already have codified standards for reporting quality events and the minimum elements suggested to be included in error reporting and go beyond what is utilized by the AHRQ. Walgreens suggested the Committee not recommend the suggested minimum elements to be included but that the AHRQ, PSOs and outlets determine elements to be included based on tasks completed and to avoid redundancy.

A representative from CPhA cautioned the Board from creating any extra elements beyond those currently used to avoid redundancy. The representative cited a similar example how all vaccine data must be reported to CAIR and added elements were added that caused a lot of issues with vaccine providers.

A pharmacist representative from Kaiser asked for the purpose of requiring a submission for pharmacy identifier or pharmacy identification code as neither ISMP Canada nor AHRQ collect that information. The representative expressed concern for collecting this information that could be misused.

A representative from a compounding pharmacy that compounds intrathecal drugs that are shipped directly to prescribers indicated it would be difficult to collect information like race and sex as that information does not come from prescribers.

A representative of CCAP agreed with all previous speakers.

A pharmacist commented certain items not listed were important to be collected (*e.g.*, work hours of personnel involved, type of pharmacy, intended or received patient, patient consultation required, pharmacist/pharmacy technician impairment, etc.). The pharmacist commented the pharmacy identifier was not needed.

Members were provided the opportunity to comment after public comment was received.

Dr. Serpa recommended considering the data elements in two groups: data elements that were similar to AHRQ and data elements that were added to supplement AHRQ. Elements that would be added need to be considered at a higher level as they represent information not currently being collected.

Dr. Oh commented in understanding the sentiment and reason to add some elements but that the intent of the legislation was to have data collected and didn't want anything to hinder the collection of data. Dr. Oh thought it would be best to keep the elements as simple as possible to match AHRQ to streamline as much as possible. Dr. Oh suggested taking the comments collected at the meeting and considering amending the quality assurance regulations once approved.

Dr. Thibeau suggested added "if known" option so that if the data is available it could be collected.

2. **Does the Committee agree that the entity will provide a process or processes to collect data from all required reporters and will report, summarize, and evaluate data to provide recommendations?**

Dr. Serpa believed it was important to have a single entity be responsible for the end-to-end process, from medication error collection through evaluation, and development of recommendations that can be used to inform pharmacists and pharmacies of practice changes to reduce errors.

Members were provided the opportunity to comment.

Dr. Oh agreed with Dr. Serpa.

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

Members of the public were provided the opportunity to comment via WebEx.

A representative of Pharmacy Affairs for Walgreens encouraged the Board to ensure none of the processes violate any elements of the Patient Safety and Quality Improvement Act (PSQIA) and reporting entities were able to access reports so that analysis and improvements can be made.

A pharmacist agreed with Chairperson Serpa that it should be a requirement to get the information back for the Board to know what is causing errors, priorities, and what regulations should be changed. The pharmacist noted if the contractor will send information back to the entities, there will need to be an entity identifier.

A representative of the Alliance for Quality Improvement and Patient Safety (AQIPS) suggested if there were recommendations, the recommendations should go to everyone to allow for learning. PSOs were required to provide individual feedback to individual providers. The pharmacy identifier wouldn't be necessary and it would be cost prohibitive to provide individual feedback as well as duplicative of the Patient Safety Act.

Chairperson Serpa reminded members that cameras needed to remain on or announce that technical difficulties were preventing the cameras from being on.

3. **Does the Committee wish to specify the frequency within which data is provided to the Board (*e.g.*, quarterly, semi-annually, annually, upon request, etc.)?**

Chairperson Serpa thought at least for the first year, there may be value in requesting quarterly reporting and that the frequency might later be able to be changed to semi-annually. Dr. Serpa also thought there was a need to be able to request data on an ad hoc basis.

Members were provided the opportunity to comment.

Dr. Oh agreed with quarterly at a minimum.

Members of the public in Sacramento and via WebEx were provided the opportunity to provide comments; however, no comments were made.

4. How frequently does the Committee prefer the entity to provide summary reports on its findings regarding trends that may be published and disseminated?

Chairperson Serpa believed summary information should be developed and released at least semi-annually, especially at the beginning as collection of the date begins.

Members were provided the opportunity to comment.

Dr. Thibeau agreed with Dr. Serpa.

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented sometimes errors require immediate response because of the serious nature of the error. The pharmacist commented there needed to be a provision in the contract that if the entity identifies something serious, the Board will be notified immediately and recommended it be included in the scope of work.

Members were provided the opportunity to comment after having received public comment.

Dr. Barker was not clear on who the information is disseminated to – does this include the consuming public. Ms. Sodergren provided the vendor would

make it available to the Board and the Board could disseminate through the Board's website and subscriber alert system.

5. **How frequently does the Committee prefer the entity to develop and disseminate information gained from the reporting to improve patient safety such as recommendations or best practices?**

Chairperson Serpa believed in some instances annual release might be sufficient but there could be certain kinds of errors that warrant a more immediate action. Dr. Serpa thought minimum frequencies should be established but then also consider requirements for release of information such as safety alerts when an error(s) reported reveal a significant risk to patients that must be addressed more quickly.

Members were provided the opportunity to comment.

Dr. Thibeau agreed on establishing a minimum and being able to send more frequently as needed. Dr. Thibeau thought maybe sending it out with *The Script* might be helpful but supported an annual minimum with more frequently releases available.

Dr. Serpa clarified this question addressed recommendations and best practices including the evaluation. Dr. Serpa thought the data would be wanted more frequently and the evaluation of the data less frequently with a minimum developed. Dr. Thibeau agreed.

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

Members of the public were provided the opportunity to comment via WebEx.

A representative from AQIPS commented the law allowed the pharmacies to report through a component PSO or other agents where PSOs work with the pharmacies to implement best practices. The representative recommended not overlooking PSOs that report to the vendor.

6. **Are there certain types of events (*e.g.*, patient death) that the Committee believes should be identified immediately and released as a safety alert within a specified timeframe?**

Dr. Serpa believed there was the potential for some issues to occur that require more immediate release of information. Dr. Serpa suggested when such an issue is identified, dissemination should be possible within a number of days of identification. She believed it was important to provide sufficient time for experts to evaluate and make recommendations that do not create new risks or have unintended consequences.

Members were provided the opportunity to comment.

Member Barker wanted to see a requirement for an immediate release for a safety alert on a quick turnaround. Dr. Serpa expressed the need to convey immediate release using a flexible standard as without imposing a deadline that might have unintended consequences.

Members of the public in Sacramento and via WebEx were provided the opportunity to provide comment; however, no comments were made.

7. How will ad hoc or custom reports be requested if further information is desired by the Board?

Dr. Serpa noted in addition to predetermined reports there was value in ensuring the Board could request ad hoc reports.

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

Members of the public in Sacramento and WebEx were provided the opportunity to provide comment; however, no comments were made.

8. Does the Committee wish to delegate a member to serve on the panel responsible for reviewing the proposals and selecting the vendor?

Dr. Serpa noted staff were asking if the Committee wished to appoint a member of the Committee to serve on the panel responsible for reviewing the proposals and selecting the vendor. Dr. Serpa indicated that she would be happy to serve as the delegate if the Committee was comfortable.

Members were provided the opportunity to comment.

Members Thibeau and Barker expressed support for Dr. Serpa serving on the panel.

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

Members of the public were provided the opportunity to comment via WebEx.

A representative of AQIPS commented it was a great idea to have a Board member participate in the process but was concerned only two presentations were heard by the Committee. The commenter thought others should be allowed to make presentations as well.

Dr. Serpa clarified that the presentations heard by the Committee today from ISMP Canada and ARHQ were to provide background information from national programs to the Committee. All organizations interested in bidding on the contract will be given the opportunity to participate through the RFP process.

A pharmacist medication safety officer suggested a flowchart or timeline to supplement the presentation provided by DCA regarding the RFP process. The pharmacist asked if possible to consider PSOs currently being used as well as exemptions.

A commenter agreed with the medication safety officer noting the commenter worked with independent and regional chain pharmacies. The commenter expressed concern if another reporting entity was required, it would be extra workload during a time when workload was trying to be reduced.

9. As the contract will be fully funded through licensees reporting to the entity, does the Committee believe the cost to be assessed to each pharmacy reporting should be a factor in determining the entity to receive the award of the bid?

Dr. Serpa strongly believed this should be a factor.

Members were provided the opportunity to comment.

Dr. Baker and Dr. Oh agreed with Dr. Serpa that the cost should be a factor in determining the entity to be awarded the contract.

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented about the cost for the entity and added there should be some latitude or necessity to apportion the cost based on the size of the reporting organization.

10. Does the Committee believe the entity needs to provide a variety of means for pharmacies (or their agents) to submit the data reports (e.g., through a portal, emailing a datafile, 3rd party such as a PSO, etc.)?

Dr. Serpa stated that she personally believed more than one option for submission was necessary. Dr. Serpa noted while some pharmacies may have staff that manage their IT systems, other may have more limited systems. Dr. Serpa believed the Committee needed to ensure that implementation is easily achievable and flexibility in the submission of reports is crucial.

Members were provided an opportunity to comment.

Dr. Oh agreed that flexibility was crucial for successful implementation of this bill.

Members of the public in Sacramento were provided the opportunity to provide comment.

A representative of Pharmapod commented in appreciation for consideration for different ways for pharmacies to report. The representative added PSOs allow for a way to reduce duplication.

Members of the public were provided the opportunity to comment via WebEx.

A representative of AQIPS commented it was important to encourage the use of PSOs. PSOs currently do this under the Patient Safety Act and are required to provide individual feedback to help pharmacies solve their own problems. The representative encouraged the use of PSOs and not providing an "either/or" scenario that might hurt the learning system.

A pharmacist commented in support of this concept noting there needed to be multiple ways for pharmacies to report and the cost must be affordable.

Dr. Serpa thanked the Committee and attendees for their time, adding if the Board agreed to delegate authority for her to work on the panel, she would use the information and discussion today when working with staff.

The Committee took a lunch break from 12:30 p.m. to 1:15 p.m. Roll call was taken. The following members were present by WebEx: Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; Nicole Thibeau, Licensee Member; and Maria Serpa, Licensee Member. A quorum was established.

VIII. Discussion and Consideration of Draft Frequently Asked Questions related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Dr. Serpa recalled as part of discussion on implementation of Assembly Bill 1286, the Committee determined that, due to the comprehensive nature of the measure, development of frequently asked questions was appropriate. Dr. Serpa reviewed the draft FAQs prepared by staff that covered the various provisions within AB 1286 and stated that she believed they were comprehensive and appropriate.

Members were provided the opportunity to comment.

Dr. Thibeau spoke in support of the FAQs and thought they were great.

Dr. Oh confirmed question number one was to include all pharmacies.

Motion: Recommend approval of the FAQs related to Assembly Bill 1286

M/S: Thibeau/Oh

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist recommended in FAQ#1 to reference the code section in the body of the answer. The commenter recommended adding examples of

changes allowed by law in FAQ#2, FAQ#9, and FAQ#10. The commenter asked if FAQ#11 included staffing. The commenter recommended clarifying FAQ#15 applied to hospitals or other pharmacies. The commenter also recommended clarifying what FAQ#16 meant by transfers.

A medication safety officer commented about FAQ#5 and FAQ#6 that generally speaking individual errors were only reported to the Department of Public Health (DPH) if they are required to be reported due to the severity or nature of the event, noting routine medication errors were not necessarily individually reported but were part of the comprehensive medication error reduction plan (MERP) overseen by DPH. The commenter requested further clarification if hospital outpatient pharmacies were exempt.

A consultant pharmacist specializing in surgical clinics asked regarding FAQ#23 if the consultant pharmacist was able to submit a certification piece of paper signed by the consultant pharmacists with the wording of the renewal to be submitted with the renewal form. The commenter was told by Ask an Inspector that was not acceptable.

Dr. Serpa recalled a discussion about adding examples could be a potential legal issue. Counsel Gartner added FAQs can only restate the law and can't interpret or further clarify existing law. Ms. Gartner recommended not providing examples.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

IX. Discussion and Consideration of Proposed Revisions to Frequently Asked Questions Regarding the Use of Mobile Units

Dr. Serpa recalled with the amendment to the statutory provisions regarding mobile units included in Assembly Bill 663, the Board needed to update the frequently asked questions to reflect the changes. Dr. Serpa reviewed and believed to be appropriate the draft revisions of FAQs prepared by staff.

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

Motion: Recommend approval of the FAQs related mobile units

M/S: Oh/Thibeau

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented that there was an example provided in FAQ#1 that was in conflict with previous information provided that examples couldn't be provided in FAQs.

A pharmacist representative of Sutter Health expressed confusion by the term "end of the day" in FAQ#8.

Members were provided the opportunity to comment after having received public comment.

Dr. Serpa inquired about the comment provided regarding FAQ#1, stating she did not think it was an example. Counsel Gartner agreed with Dr. Serpa, stating that she respectfully disagreed with the commenter that an example was provided in FAQ#1.

Dr. Serpa asked the Committee if they would like to clarify FAQ#8. Members agreed in concept with updating the language to clarify.

Revised
Motion: Recommend approval of the FAQs regarding mobile units with amendments to FAQ#8 consistent with Committee discussion.

M/S: Oh/Thibeau

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

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

X. Discussion and Consideration of Draft Self-Assessment Form for Surgical Clinics

Dr. Serpa provided another part of the implementation for Assembly Bill 1286 related to the establishment of a self-assessment process for surgical clinics and referenced the draft self-assessment form for consideration in the meeting materials. Dr. Serpa thanked staff and counsel for their work on the draft. Dr. Serpa explained that because the self-assessment process for surgical clinics was established in statute versus regulation, the Board will not need to incorporate the form by reference in regulation and the approval process will be streamlined. Dr. Serpa added if members were comfortable with the provisions contained in the form, she could work with staff to finalize it.

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

Motion: Recommend approval of the draft surgical clinic self-assessment form

M/S: Oh/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist consultant specializing in surgical clinics commented all surgical clinics should be registered through the Board of Pharmacy. The pharmacist reviewed the self-assessment form in detail. The commenter

added there was no way to pre-submit the comments requesting that be added in the future. The pharmacist asked how the form should be completed if the clinic represented two of the types of clinics represented on the form. The commenter requested clarification if clinics can purchase from retail pharmacies. The commenter asked if the wholesaler provides DSQCA information on the website are the clinics required to have on paper. The commenter stated the prescriber requirements were roles outside of the surgical clinics' scope but to the prescribers who are not the employees of surgical clinics and recommended removing 5.7, 5.8, and 5.9. The wording in the self-assessment for consultant pharmacist inventory review differs from the law. The commenter recommended changing "pharmacy" to "surgical clinic" in 7.8. Additional lines needed to be provided in section 8.

A pharmacist representative from Sutter Health commented on the word "handles" in 8.5 and questioned how this would be interpreted.

Dr. Serpa reiterated the self-assessment was to re-state current law and no additional information was to be provided. Dr. Serpa thought sections 5.7, 5.8, and 5.9 were appropriate but public comment indicated otherwise. Ms. Sodergren believed inclusion was appropriate as it was vetted with the counsel prior to the meeting and would be happy to ask counsel to review the three items. Dr. Serpa believed 6.6 should be checked for agreement with the law. Dr. Serpa said additional lines could be added to 8.2. Ms. Sodergren, Dr. Oh, and Dr. Barker recommended additional pages could be added. Dr. Serpa noted the title of USP 800 contained the word "handling."

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

Revised Motion: Recommend approval of the draft surgical clinic self-assessment form and delegate to the Committee chair to finalize the form with staff and counsel prior to presenting to the Board for final approval.

M/S: Oh/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist consultant for surgical clinics asked when the next draft form would be available for review.

A pharmacist commented 5.7 was related to the ability to be licensed by the Board to buy drug stock as an entity while other prescribers can be employed by the clinic for 5.9. The pharmacists thought they were appropriate for inclusion in the self-assessment form.

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

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Support

XI. Discussion, Consideration, and Possible Action on Self-Assessment Forms 17M-13, 17M-14, and 17M-26
a. Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment Form 17M-13 (Cal. Code Regs., tit. 16, § 1715(c))
b. Hospital Pharmacy Self-Assessment Form 17M-14 (Cal. Code Regs., tit. 16, § 1715(c))
c. Wholesaler/Third-Party Logistics Provider Self-Assessment Form 17M-26 (Cal. Code Regs., tit. 16, § 1784(c))

Dr. Serpa recalled in February 2023, the Board voted to update the community pharmacy, hospital pharmacy, and wholesaler/third party logistics provider self-assessment forms through a streamlined section 100 regulation process. At that time, the Board believed that given the forms restate law and do not create requirements not already established in statute and regulation, such an approach was possible. Regrettably, the Board was recently advised by the Office of Administrative Law that it could not use the streamlined process. Dr. Serpa continued that for the Committee's review today were updated versions of the three forms. As the forms do not create laws, rather restate law, Dr. Serpa believed the focus could be on the approval of the forms to the provisions that were incorporated. Dr. Serpa reviewed all three forms and believed they were

appropriate.

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

Member Thibeau left the meeting at 1:59 p.m.

Motion: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, sections 1715 and 1784 as proposed to be amended and self-assessment forms 17M-13, 17M-14, and 17M-26 incorporated by reference. Authorize the executive officer to further refine the language consistent with the Committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

M/S: Oh/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist representative of Kaiser commented about the community pharmacy self-assessment at 6.14 and the hospital pharmacy self-assessment at 7.11 restating the pharmacist's professional continuing education requirement as well as community pharmacy self-assessment at 9.9 and hospital pharmacy self-assessment at 10.12 restating the pharmacy technician continuing education requirement on cultural competency. The representative encouraged the Committee to think how restating the requirement would help the pharmacist-in-charge (PIC) of the pharmacy and consider removing these items from the self-assessments. The representative added the PIC shouldn't be validating this requirement.

Members were provided the opportunity to comment after having received public comment; however, no comments were made.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Serpa	Support
Thibeau	Not Present

XII. Discussion and Consideration of Enforcement Statistics

Chairperson Serpa referred to meeting materials that included a summary of enforcement statistics for the first six months of the fiscal year. The Board received 1,639 complaints and closed 1,371 investigations. The Board revoked 35 licenses, accepted the disciplinary surrender of nine licenses, formally denied two applications, and imposed other levels of discipline against 33 licensees and/or applicants. As of January 1, 2024, the Board had 1,582 field investigations pending. The materials provided a breakdown of the average timeframe for the various stages of the field investigation process.

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

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

XIII. Future Committee Meeting Dates

Chairperson Serpa thanked everyone for their time and participation, noting the next meeting was currently scheduled for April 11, 2024. Dr. Serpa asked that stakeholders monitor the Board's website for updates.

XIV. Adjournment

The meeting adjourned at 2:07 p.m.