

#### California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

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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
Public Board Meeting Minutes

Date: December 2, 2021

**Location:** Teleconference Public Board Meeting

Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations

are provided.

**Board Members** 

**Present:** Seung Oh, Licensee Member, President

Maria Serpa, Licensee Member, Vice President

Jignesh Patel, Licensee Member, Jose De La Paz, Public Member Lavanza Butler, Licensee Member Ricardo Sanchez, Public Member Nicole Thibeau, Licensee Member

Jason Weisz, Public Member Debbie Veale, Licensee Member

**Board Members** 

**Absent:** Shirley Kim, Public Member

**Staff Present:** Anne Sodergren, Executive Officer

Eileen Smiley, DCA Staff Counsel Sheila Tatayon, DCA Staff Counsel

## I. <u>Call to Order, Establishment of Quorum, and General Announcements and Recognitions</u>

The meeting was called to order at 9:03 a.m. President Oh reminded everyone that the meeting was being conducted consistent with the provisions of Government Code section 11133. Provisions for providing public comment throughout the meeting were reviewed.

DCA staff provided instructions for providing public comment throughout the meeting.

California State Board of Pharmacy Board Meeting Minutes – December 2, 2021 Page 1 of 17 President Oh advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present included Maria Serpa, Jignesh Patel, Jose De La Paz, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, and Seung Oh. A quorum was established.

#### II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda. Paul Cummings, commented on the Board's probation program. He completed probation and thanked the Board and Inspector Simari. He appreciates the Board giving pharmacists a second chance and noted that probation works and helped him become a better pharmacist. Mr. Cummings noted that it was difficult to find employment while on probation.

Dr. Simonian works with pharmacists promoting the safe use of cannabis including education. Dr. Simonian indicated that guidelines have been developed to assist with the provisions of Senate Bill 311 and requested that this topic be placed on a future agenda item.

Members were surveyed to determine if any of the items should be placed on a future agenda. Member De La Paz, requested that Senate Bill 311 be placed on a future agenda for the enforcement committee. It was seconded by Nicole Thibeau.

Member Butler joined the meeting at 9:15.

**MOTION:** Schedule discussion on Senate Bill 311 related to education on the use of cannabis at a future Enforcement Committee meeting.

#### M/S: De La Paz/Thibeau

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 0

| Board Member | Vote        |
|--------------|-------------|
| Butler       | Support     |
| De La Paz    | Support     |
| Kim          | Not present |
| Oh           | Support     |
| Patel        | Support     |
| Sanchez      | Support     |
| Serpa        | Support     |
| Thibeau      | Support     |
| Veale        | Support     |
| Weisz        | Support     |

President Oh reminded members of the creation of an ad hoc committee to consider standard of care.

### III. Presentation by Dr. Rita Shane on Quality Improvement Study Conducted on Senate Bill 1254

Dr. Shane provided background and history on the issue including the process to collect medical history and the problems with incomplete medication lists. SB 1254 the bill became effective January 1, 2019.

Following enactment, Dr. Shane conducted a study to determine the number of medication errors identified and intercepted as a result of the change. Dr. Shane reviewed the methodology for the quality improvement study. Eleven organizations participated in the study. The study used the NCC MERP wheel was used to ensure consistency with the reporting of the types of errors.

Dr. Shane noted that 2, 273 medication histories were documented with a total of 15,850 errors noted. Dr. Shane highlighted data including 94 percent of the medication histories had at least one error and 54 percent of the patients who had a potential serious or life-threatening error.

Dr. Shane provided examples of the types of errors avoided through the use of the medication reconciliation process.

Dr. Shane noted that California is the only state that has implemented such a requirement. Dr. Shane shared cost savings stemming from the errors averted.

Members were provided the opportunity to ask questions. Members noted the impressive outcomes and cost impacts. In response to a question, Members were advised of a study underway at Cedars evaluating medication errors avoided through pharmacist review at the time of discharge.

Members of the public were provided the opportunity to provide public comments. Dr. Gray suggested that very few hospitals have implemented Senate Bill 1254 and inquired what needs to be done to strengthen enforcement.

Public comment included an inquiry about if the results will be published.

#### IV. Discussion and Consideration of Results of Workforce Survey

Members received a presentation on the results of the workforce survey from Ms. Sodergren and Dr. Tracy Montez. (A copy of the presentation slides is available on the Board's website as part of the meeting materials.)

Dr. Montez noted the benefits of surveys in that they can reach a broad group of individuals; however, the surveys are typically self-report and the accuracy of the information is dependent on the responses and the overall response rate.

Members were provided with summary demographic data on survey respondents. Members were reminded that the survey was designed to assess the working conditions in community pharmacies in California, noting that over 2,900 pharmacists that completed the survey reported working in a chain community pharmacy, 407 reported working for an independent pharmacy and over 900 reported working in another setting. The remainder of the data reviewed would be limited to respondents that identified as working in either a chain community pharmacy or independent community pharmacy. Further, some data responses were further broken down by staff pharmacists versus those that work as a pharmacist-in-charge.

As part of the presentation, Dr. Montez highlighted findings that were statistically significant. Examples included responses to Question 18 "Do you believe you have sufficient time to provide adequate screening prior to the administration of an immunization" where 78 percent community chain pharmacists reported they did not have sufficient time, whereas 56 percent of independent community pharmacists reported yes to having sufficient time. Further a statistically significant finding included the responses to the question, "Does your primary worksite employer use workload metrics in specified areas?" which reveal chain pharmacies are more likely to use workload metrics than independent pharmacies.

Survey results also indicate that in response to the question, "Do you believe you have sufficient time to provide appropriate patient consultation?" again revealed a statistically significant finding with community chain pharmacists report they do not have sufficient time while, 68 percent of pharmacists working in an independent pharmacy reported they did have sufficient time. Results also indicated that in response to the question, "Do you believe the pharmacy staffing in your primary worksite is appropriate to ensure adequate patient care?" 91 percent of pharmacists working in a community chain pharmacist responded no, while 68 percent of pharmacists working in an independent community pharmacy responded yes.

Member Butler requested to be placed on the new ad hoc committee. Member Thibeau stated appreciation for how the information was presented and requested to be placed on the medication error reduction committee.

Members of the public were provided an opportunity to provide public comment. Dr. Gray suggested that PIC for the independent pharmacy should be assessed to determine if they are also the owner. He also questioned what is included in "chain."

Keith Yoshizuka, CSHP, applauded the Board for looking into this issue.

Following public comment, the meeting was in recess from about 10:35 a.m. to 10:45 a.m.

Upon return, roll call was taken. Members present included: Jignesh Patel, Cheryl Butler, Jose De La Paz, Nicole Thibeau, Debbie Veale, Jason Weisz, Maria Serpa, Ricardo Sanchez and Seung Oh.

V. Discussion and Consideration of Application and Enforcement of Business and Professions Code section 688 Related to Forwarding of Controlled Substance Prescriptions, Including Potential Statutory Amendments.

President Oh referenced the meeting materials and reminded members e-prescribing requirements become effective January 1, 2022. As part of its implementation efforts the Board has provided education on the requirements, including development of frequently asked questions which are posted on the Board's website.

Recently, as part of public comment, the Board received a request to further discuss the provisions related to unfilled schedule II-V controlled substances prescriptions and the requirements to transfer or forward such electronic prescriptions.

President Oh advised members of the development of a statutory change that could be one means to address the concerns raised. Dr. Oh referenced the DEA released a proposed rule related to the transfer of electronic prescriptions for scheduled controlled substances between pharmacies. Dr. Oh noted that this rule could address some of the challenges that have been expressed from stakeholders and members. .

Ms. Veale suggested that the Board needs to simplify the language.

Dr. Serpa noted that the issue is a national issue and the amount of time and effort required to effectuate the change. Dr. Serpa suggested it may be pre-mature especially given the changes that are happening at the national level. Dr. Serpa suggested holding off for a few months.

Member Butler questioned if a pharmacy will have the ability to transfer a prescription and asked if holding off will impact her ability to have a prescription transferred.

Member Thibeau requested clarification on the proposal. Ms. Smiley reiterated the requirements of the law, the current problem, the solution being offered, as well as, the need for the transition period.

Members of the public were provided the opportunity to provide public comment. Danny Martinez, CPhA, indicated he does not believe there is a need for the transition period.

Lindsay Gullihorn, CRA and NACDS, thanked the Board for considering this issue, indicated support for the legislative fix, and suggested an urgency measure may be necessary noting that enforcement discretion is necessary while the statutory change is underway.

Steven Gray, indicated that one portion of the provision would eliminate the ability to transfer the request if there is not an NCPDP standard developed, even if the prescription was an oral prescription.

John Gray, Kaiser, appreciated the Board's consideration and suggested that the Board provide clarity for the time point. Dr. Gray offered language and spoke in support of the one-year delay and requested inclusion of an urgency provision in the language.

Keith Yoshizuka, CSHP, noted appreciation the Board's progressive position in a number of areas, but suggests that the Board should consult with the New York Board of Pharmacy as that entity may be able to provide some language.

Mark Johnston, CVS Health, noted appreciation for the Board's effort.

**MOTION:** Pursue a statutory change to BPC 688(g) with a one-year delay following the necessary change in law or standards. Delegate to EO and President to finalize the language and work through the statutory process.

#### M/S: Veale/Patel

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

Support: 8 Oppose: 0 Abstain: 1 Not Present: 1

| Board Member | Vote        |
|--------------|-------------|
| Butler       | Support     |
| De La Paz    | Support     |
| Kim          | Not present |
| Oh           | Support     |
| Patel        | Support     |
| Sanchez      | Support     |
| Serpa        | Support     |
| Thibeau      | Support     |
| Veale        | Support     |
| Weisz        | Abstain     |

# VI. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, CCR Section 1715.65, Inventory Reconciliation and Discussion and Consideration of Public Comments Received during the 45-day Comment Period.

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions.

President Oh acknowledged all had the opportunity to review the meeting materials including the comments received and staff recommendations. Dr. Oh advised Ms. Tatayon and Ms. Smiley were present to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

President Oh stated after reviewing the comments, he agreed with the recommendations of staff. Members were provided the opportunity to provide comment; however, no comments were made.

Dr. Serpa commented to the rest of the Board that this regulation is complex and that it has been in discussion. Dr. Serpa noted agreement with the proposed language. Dr. Serpa moved and Cheryl seconded with the motion and language as presented.

Member Veale, stated appreciation for the clean-up done on the language and suggested from a construction standpoint if (a)(3)(b) may be in the wrong place. Ms. Tatayon discussed how the language is constructed and how it is appropriate.

Dr. Serpa noted that the intent in (3)(B) was to require the reconciliation report for any loss.

Member Veale expressed concern with the requirement for signature. Further Ms. Veale sought clarification on (e) and (h). Dr. Serpa noted that outside of the hospital

setting, there are different requirements because there could be an unknown discrepancy necessitating the need for the physical count.

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

John Gray, Kaiser, suggested the terms acquisition and disposition needs to be defined and indicated that misapplication could occur.

Dr. Yoshizuka expressed concerns with the additional work that this regulation would require.

Paige Talley, California Council for the Advancement of Pharmacy, noted appreciation for Member Veale's comment that all ADDSs be included in the provision and request future consideration for other ADDS in other settings.

Mark Johnston, requesting a one-year delay. He restatement the comments submitted and administrative burdens.

#### Motion:

Accept the Board staff recommended comment responses, approve the staff recommended modified regulation language, and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1715.65 as noticed. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Proposed changes to the current regulation language are shown by strikethrough for deleted language and <u>underline</u> for added language.

Modified changes to the current proposed language are shown by <del>double</del> <del>strikethrough</del> for deleted language <u>and double underline</u> for added language.

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. <u>Inventory Activities and Inventory Reconciliation Reports</u> of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory <u>activities</u> and <u>prepare</u> inventory reconciliation <u>functions reports</u> to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g),

- inventory reconciliation reports shall be prepared on the following ongoing basis:
- (1) For federal Schedule II controlled substances, at least once every three months.
- (2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
- (A) Alprazolam, 1 milligram/unit.
- (B) Alprazolam, 2 milligrams/unit.
- (C) Tramadol, 50 milligrams/unit.
- (D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
- (3) (A) For any controlled substance not covered by paragraph (1) or (2), an inventory reconciliation report shall be prepared for identified controlled substances lost no later than three months after discovery of the any-loss of that controlled substance. This report shall be completed if the loss is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery. At a minimum, any pattern(s) of loss(es) identified by the pharmacist in charge shall require an inventory reconciliation report for each pattern of loss identified, as defined by the pharmacy's policies and procedures. Any reportable loss, as specified in section 1715.6, shall also require an inventory reconciliation report.
- (B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary sufficient to identify losses of the controlled substances. The functions sufficient to identify loss outside of the inventory reconciliation process shall be identified within the pharmacy's policies and procedures.
- (b) The pharmacist-in-charge of a pharmacy or-consultant consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports taken prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled drugs substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory reconciliation reports required by this section.
- (c) A pharmacy or clinic shall compile an An inventory reconciliation report-of all federal Schedule II controlled substances at least every three months. This compilation prepared pursuant to this section shall require include all of the following:
- (1) A physical count, not an estimate, of all quantities of federal Schedule II each federal controlled substances substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The

biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

- (2) A review of all acquisitions and dispositions of <u>each</u> federal <u>Schedule II</u> controlled <u>substances</u> <u>substance</u> covered by the <u>report</u> since the last inventory reconciliation report covering that controlled substance;
- (3) A comparison of (1) and (2) to determine if there are any variances;
- (4)—All Identification of all records used to compile—each inventory reconciliation the report, which shall be maintained in the pharmacy or clinic—for at least three years in a readily retrievable form pursuant to subdivision (e)(2);—and (5) Identification of each individual involved in preparing the report; and (5)—(6) Possible causes of overages—shall be identified in writing and incorporated into the inventory reconciliation report.
- (d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances. (e)(1) The An inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-incharge or professional director (if a clinic)-and, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if. in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2). (2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. A countersianature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.
- (f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report-as identified in subdivision (c) for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible, an outgoing pharmacist-in-charge should also complete an inventory reconciliation report-as required in subdivision (c) for those controlled substances.
- (g) For Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies, shall prepare an inventory reconciliation report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on

a separate quarterly inventory reconciliation report shall be required for federal Schedule II basis. The report or reports shall include controlled substances stored within the pharmacy-and for, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. (h) The pharmacist-in-charge of If an inpatient hospital pharmacy-or of a pharmacy servicing onsite or offsite uses an automated drug delivery-systems system (ADDS), inventory in the ADDS may be accounted for under subdivision (c) (1) using means other than a physical count.-shall ensure that:

- (1) All controlled substances added to an automated drug delivery system are accounted for;
- (2) Access to automated drug delivery systems is limited to authorized facility personnel:
- (3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
- (4) Confirmed losses of controlled substances are reported to the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

**M/S:** Serpa/Butler

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

| Board Member | Vote        |
|--------------|-------------|
| Butler       | Yes         |
| De La Paz    | Yes         |
| Kim          | Not present |
| Oh           | Yes         |
| Patel        | Yes         |
| Sanchez      | Yes         |
| Serpa        | Yes         |
| Thibeau      | Yes         |
| Veale        | Yes         |
| Weisz        | Yes         |

# VII. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, CCR Section 1746.5 Vaccine Administration of Public Comments Received during the 45-day Comment Period.

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions.

President Oh acknowledged all had the opportunity to review the meeting materials including the comments received and staff recommendations. Dr. Oh advised Ms. Tatayon and Ms. Smiley were present to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

President Oh stated after reviewing the comments, he agreed with the recommendations of staff. Members were provided the opportunity to provide comment; however, no comments were made.

The public was provided with the opportunity to provide public comment; however, none were provided.

#### Motion:

Accept the Board staff recommended comment responses and adopt the regulation language as noticed on October 8, 2021. Additionally, authorize the Executive Officer to take all steps necessary to complete the rulemaking and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

## To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Legend: Insertions are Underlined; Deletions are Stricken

#### § 1746.4. Pharmacists Initiating and Administering Vaccines.

- (a) A pharmacist initiating and/or administering any vaccine pursuant to section 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.
- (b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
- (1) Completion of an approved immunization training program, and
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

- (c) Continuing Education: A pharmacist must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.
- (d) Notifications: At the request of a patient, A a pharmacist shall notify, each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If a patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.
- (e) Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3), of the Business and Professions Code, the information described in section 120440, subdivision (c), of the Health and Safety Code within 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subdivision (e), of the Health and Safety Code.
- (f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide each patient with a vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052, 4052.8 and 4081, Business and Professions Code; Section 120440, Health and Safety Code; and Section 300aa-25, Title 42, United Stats Code.

**M/S:** Veale/Butler

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 1

| Board Member | Vote        |
|--------------|-------------|
| Butler       | Support     |
| De La Paz    | Support     |
| Kim          | Not present |
| Oh           | Support     |
| Patel        | Support     |
| Sanchez      | Support     |
| Serpa        | Support     |
| Thibeau      | Support     |
| Veale        | Support     |
| Weisz        | Support     |

# VIII. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, CCR Section 1715.6, Reporting Drug Losses to Address Comments from the Office of Administrative Law

President Oh referenced the meeting materials for the regulation and commented in appreciation of the detailed responses to the comments received along with the relevant statutory provisions. Dr. Oh provided background on the issue and noted that staff prepared the recommended text to address the concerns expressed by OAL.

Dr. Oh advised Ms. Tatayon and Ms. Smiley were present to answer any legal questions on the language, comments received, and staff recommendations developed in response to comments.

Dr. Serpa noted the minor modifications and spoke in support.

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

Motion: Approve the recommended modified regulation language and initiate a 15-day public comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to adopt the proposed regulations at Section 1715.6 as noticed and take all steps necessary to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Proposed changes to the current regulation language are shown by strikethrough for deleted language and <u>underline</u> for added language.

Modified changes to the proposed regulation language are shown by <del>double</del> <del>strikethrough</del> for deleted language and <u>double underline</u> for added language.

### Amend Section 1715.6 to Title 16 of the California Code of Regulations, to read as follows:

#### § 1715.6. Reporting Drug Loss.

- (a) The owner shall <u>submit report</u> to the Board <u>a report containing the information in subdivision (b) within no later than thirty (30) days <u>after the date</u> of discovery of <u>the following:</u></u>
  - (1) any Any loss of the a controlled substances, including their in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed:

    (A) For tablets, capsules, or other oral medication, 99 dosage units.
    - (B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.
    - (C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.
  - (2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft, in addition to the reporting requirements and time frames mandated by Business and Professions Code section 4104.
  - (3) Any other significant loss as determined by the pharmacist-in-charge, including but not limited to losses deemed significant relative to the dispensing volume of the pharmacy.
- (b) All reports under this section shall specify the identity, amounts and strengths of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, and 4332, Business and Professions Code.

M/S: Serpa/Veale

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 1

| Board Member | Vote        |
|--------------|-------------|
| Butler       | Support     |
| De La Paz    | Support     |
| Kim          | Not present |
| Oh           | Support     |
| Patel        | Support     |
| Sanchez      | Support     |
| Serpa        | Support     |
| Thibeau      | Support     |
| Veale        | Support     |
| Weisz        | Support     |

Roll call taken at 1:03. Members present included: Maria Serpa, Jignesh Patel, Cheryl Butler, Jose De Le Paz, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, Jason Weisz, Seung Oh

## IX. Petitions for Reinstatement of Licensure, Early Termination or Other Modification of Penalty

Administrative Law Judge Heather Rowan presided over the following petition hearings:

- a. James Poon, RPH 74515
- b. Jessica Jin Hee Park, RPH 71655
- c. Saifuddin Hatim Raniwala, RPH 49936

The Board took a break from 2:26 p.m. to 2:35 p.m. Roll call was taken after the break. Members present included Seung Oh, Maria Serpa, Cheryl Butler, Jignesh Patel, Jose De La Paz, Ricardo Sanchez, Nicole Thibeau, Debbie Veale, and Jason Weisz. A quorum was established.

#### X. Closed Session Matters

The Board recessed into closed session at approximately 3:35 p.m.

#### XI. Adjourn

The Board adjourned after closed session at approximately 4:15 p.m.