TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter: Inventory Reconciliation Report of Controlled Substances

Sections Affected: Add section 1715.65 of Article 2 of Division 17 of Title 16 California Code of Regulations (CCR).

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the adoption of the above sections, and is updated to include the following information. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested.

The 45-day public comment period began on September 16, 2016 and ended on October 31, 2016. No request for a hearing was received by the Board during the 45-day comment period, and no hearing was held.

During the 45-day comment period, the Board received numerous comments. The Board considered these comments at its meeting held December 14, 2016. In response to the comments received, the Board voted to modify the text and initate a 15-day public comment period.

The modified text was noticed for a 15-day comment period that began on December 23, 2016 and ended on January 7, 2017. During that time, the Board received numerous comments. The Board considered these comments at its meeting held January 24-25, 2017. In response to the comments received, the Board voted to return the regulatory proposal to the Enforcement Committee for further review and consideration.

The regulatory proposal was discussed at its public committee meeting held April 18, 2017. The committee presented recommendations to the Board for consideration at its meeting held May 3-4, 2017. In response to the committee's recommendation, the Board voted to modify the text and initate a second 15-day public comment period.

The modified text was noticed for a second 15-day comment period that began on May 16, 2017 and ended on May 31, 2017. During that time, the Board received numerous comments. The Board considered these comments at its meeting held July 25-26, 2017. No additional changes were made in response to the comments received during the second 15-day comment period.

After having considered all comments in the record, the Board adopted the regulation, as noticed on May 16, 2017.

The regulation was modified from the original proposed text as follows:

Non-substantive changes were made throughout the regulation to correct punctuation and typographical errors, correct capitalization for consistency, and to update subdivision numbering as necessary for the addition or deletion of text.

Subdivision (c), subdivision (c)(1), and subdivsion (c)(2) were amended to add “federal” before Schedule II controlled substances in both subdivisions. This terminology is added for clarity. The State of California and the Federal Government each have their own drug schedules. The Board determined the federal Schedule II is the most current and complete drug schedule, as State schedule II has not been amended since 2010. Additionally, the federal Schedule is the standard for the purpose of reporting to the Controlled Substance Utilization Review and Evaluation System (CURES), as defined in Health and Safety Code section 11165(d).

Subdivision (c)(5), was moved from a different subdivision to make it clear that overage causes should be documented as part of the same inventory reconciliation report identified in subdivision (c), with other requirements, was amended to read “Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.” The term “possible” replaced “likely” for clarity. The licensee need not identify the most “probable” cause of the overage, which may be difficult to determine; by requiring the licensee to memorialize “possible” causes, it will make it more likely the licensee focuses on the analysis rather than assessing likelihood. Focusing on the analysis makes it more likely that they will have more accurate counts in the future.

Subdivision (d) was amended to require “known” causes of losses identified in the inventory reconciliation report be reported to the Board instead of “possible” causes for clarity. Additionally, the subdivision was amended to add that the reporting be done within 30 days, unless the cause is theft, diversion, or self-use. In those cases the reporting requirement is 14 days, which makes it consistant with the reporting requirements as specified in Business and Professions Code (B&P) section 4104, and CCR section 1715.6. This section in part duplicates some requirements from B&P section 4104 and CCR section 1715.6. To the extent the requirements in the section is duplicative with either the timing requirements and/or drug loss reporting requirements in B&P Section 4104 (for employees) or CCR, Title 16, Section 1715.6 (reporting of all controlled drugs) this duplication is necessary for clarity. This clarifies for the regulated public drug loss reporting requirements as they relate to the losses identified as part of an inventory reconciliation report. The subdivision was also amended to add a requirement that the licensee conduct further investigation to identify the cause of the loss and any actions necessary to prevent additional losses of controlled substances in the future. This requirement was previously located in subdivision (h)(5) and was relocated to (d) for clarity as it applies to all pharmacies and clinics, and not just inpatient hospital pharmacies and automated drug delivery systems. Finally, the “security improvement” language was removed because the loss may not be due to a security issue, and requiring security improvements may not be appropriate. The requirement to notify the Drug Enforcement Administration (DEA) was also removed since the DEA reporting requirements are clear in federal law.

Subdivision (e) was amended to add “or professional director (if a clinic)” after countersigned by the pharmacist-in-charge. This change was necessary for clarity because under the provisions of pharmacy law, a professional director, not a pharmacist, is responsible for the operations of a licensed clinic. Additionally, “A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report” was added to eliminate the need for a countersignature when the pharmacist-in-charge or professional director personally completed the reconciliation. This is because the pharmacist-in-charge or professional director who personally completes the inventory reconciliation report will already be aware of its contents and, as the person responsible for the control and security of controlled substances in the pharmacy or clinic, can take any necessary corrective actions. Additionally, in the instance of a small pharmacy, there may not be another pharmacist on staff to countersign.

Subdivision (f) was amended to add “reconciliation report” after inventory in two locations to make it clear that it is not just the counting of drugs that must occur, but completing a written report. Additionally, the first sentence was restructured and “within 30 days of becoming a pharmacist-in-charge” was moved from the middle to the end of the sentence. Finally, the term “also” was added to the second sentence to clarify that the inventory reconciliation report completed by the outgoing pharmacist-in-charge (PIC) is in addition to the inventory reconciliation report completed by the new PIC. The Board determined that the new PIC should still complete the inventory reconciliation report if one was completed by the outgoing PIC to ensure accuracy of the records and accountability of the drug stock.

Subdivison (g) was amended to add “quarterly” in front of inventory reconciliation report and “federal” in front of Schedule II. These changes were made for consistency within the regulation to align subdivision (g) and subdivision (c).

Subdivision (h)(5) was relocated to subdivision (d), as mentioned above.

The reference section was updated to appropriately identify all the proper references. This update included adding sections 4008, 4037, 4080, 4101, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, and 4192 of the Business and Professions Code and 1261.6 of the Health and Safety Code.

After Board approval, a nonsubstantive change was made to subdivision (a) to clarify that sections 4180 and 4190 are in the Business and Professions Code.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

The Board’s proposal may affect small businesses; however, the Board does not have nor does it maintain data to determine if any of its licensed pharmacies or clinics are “small businesses” as defined in Government Code section 11342.610. Clinics licensed pursuant to Business and Professions Code section 4180 are likely excluded by Government Code section 11342.610(b)(6).

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The following alternatives were considered and rejected for the reasons set forth below:

1. Do not seek a regulatory change
2. Require less frequent inventory (bi-annual or annual)

Reason for rejection: The board's highest priority is the protection of the public while exercising its licensing, regulatory, and disciplinary functions. This regulatory change is part of the Board's efforts to combat drug loss and diversion from within pharmacies and prescription drug abuse within California. The Board considered several frequencies. The board determined quarterly struck an appropriate balance between the workload associated with completing an inventory reconciliation while minimizing the amount of drug losses that could occur between reconciliations. By requiring at least a quarterly inventory and analysis of all federal Schedule II controlled substances, pharmacists-in-charge, pharmacies, and clinics will be better equipped to spot and stop losses from the pharmacy earlier and prevent excessive drug losses from occurring. This will reduce the supply of controlled substances available for misuse and abuse without denying pain relief to those that need it.

Objections or Recommendations/Responses to Comments

Please see the attachments containing a summary of the comments and the Board's responses.

45-Day Public Comment Period

During the 45-day comment period and regulation hearing (September 16, 2016 - October 31, 2016, the Board received numerous comments. On December 14, 2016, the comments were reviewed and discussed at its Board meeting. Numerous changes were made to address some of these comments and the Board voted to initiate a 15-day comment period.

First Modified Text

During the first 15-day comment period (December 23, 2016 – January 7, 2017), the Board received numous comments. The Board considered these comments at its meeting held January 24-25, 2017. In response to the comments received, the Board voted to return the regulatory proposal to the Enforcement Committee for further review and consideration. The regulatory proposal was discussed at its public committee meeting held April 18, 2017. The committee presented recommendations to the Board for consideration at its meeting held May 3-4, 2017. In response to the committee's recommendation, the Board voted to modify the text and initate a second 15-day public comment period.

Second Modified Text

During the second 15-day comment period (May 16, 2017 – May 31, 2017), the Board received numerous comments. On July 26, 2017, the comments were reviewed and discussed at its Board meeting. No changes were made in response to these comments.

At its July 2017 meeting, the Board, after having considered all of the comments, voted to adopt the inventory reconciliation regulation text as it was noticed on May 16, 2017.

Finding of Necessity

The Board of Pharmacy hereby finds that it is necessary for the public health, safety, and welfare of the people of California that this regulation apply to business.