TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Reporting Drug Losses

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1715.6

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 amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on June 4, 2021 and ended on July 19, 2021. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period several comments were received. At its July 29, 2021 Board meeting, the Board adopted the regulation text as noticed on June 4, 2021.

On December 2, 2021, the Board voted to amend the regulation text and release the modified text for a 15-day comment period. The regulation text was modified as follows:

Subsection (a)(2) was amended to specify that the reporting requirements within (a)(2) with respect to the loss of controlled substances attributed to employee theft are in addition to the requirements of Business and Professions Code (BPC) section 4104, which is specific to licensed employee theft. This addition provides clarity that licensed employee theft must still be reported consistent with BPC 4104.

Subsection (a)(3) was amended to add "including but not limited to losses deemed significant relative to the dispensing volume of the pharmacy." This addition identifies one possible situation in which a drug loss under the threshold established in (a)(1)(A)-(C), may be deemed significant by the pharmacist-in-charge (PIC) and require reporting. Prior Board policy discussion detailed the use of the term "significant" for consistency with the terminology used by the Drug Enforcement Agency (DEA) while allowing for professional judgment of the PIC to determined what is significant to the specific pharmacy outside of the thresholds established by the Board (Underlying data - January 9, 2020 Enforcement Committee meeting and January 29-30, 2020 Board meeting).

The 15-day public comment period began on December 3, 2021 and ended on December 18, 2021. During the 15-day comment period no comments were received. As no comments were received, the regulation was adopted by the Executive Officer per the delegation issued by the Board on December 2, 2021.

Local Mandate

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

Small Business Impact

While the Board does not have, nor does it maintain, data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the Board has made the determination that this proposal will not have a significant adverse impact directly affecting small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the Board does not anticipate any adverse economic impact, including the ability of California businesses to compete with businesses in other states. And, the time savings will most likely have a positive financial effect upon smaller pharmacy businesses, as they have less staff available to complete forms currently necessary to report insignificant drug losses to the Board.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, 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 Board considered the following alternatives:

The Board considered aligning the regulation with the DEA's requirement of reporting theft and "significant" losses. However, the Board determined that the term "significant" was ambiguous and that additional clarity was needed; as such, the Board rejected this alternative and adopted the proposed language.

Objections or Recommendations/Responses to Comments

During the public comment period from June 4, 2021 to July 19, 2021, the Board received several comments. The comments were provided in the meeting materials for the July 28 and 29, 2021 board meeting, and the Board reviewed and considered them.

Summarized 45-day Comments Regarding Reporting Drug Losses:

Written Comments from Flynn Lew, PharmD.

Comment 1: The commenter indicated that there is no quantity specified for oral liquid-controlled substances and recommended that this be addressed.

Response to Comment 1: The Board reviewed this comment and did not make any changes to the text based thereon. The Board notes that subsection (a)(1)(A) states "other oral medication" which would apply to oral liquid-controlled substances.

Written Comments from Dale Costantino, PharmD.

Comment 1: The commenter recommended that the quantities of controlled substance losses be changed from an absolute value to a percentage of doses dispensed to "normalize the burden and criteria for reporting" across large and small pharmacies.

Response to Comment 1: The Board reviewed this comment and did not make any changes to the text based thereon. The Board previously discussed reporting percentages and determined that losses should not be reported as a percentage as the loss of 100 pills is a significant loss no matter the size of the pharmacy when public welfare is considered. Current law requires a single dose loss to be reported. This proposal eliminates the reporting of single dose losses.

Written Comments from BJ Bartleson, California Hospital Association

Comment 1: The commenter expressed concern about the administrative burden to maintain single dose losses as well as having to tabulate the losses over the one-year reporting time frame. The commenter recommends that subsection 1715.6(a)(1) be amended to remove the aggregate total requirement as the commenter believes it creates a cumbersome manual tracking process.

Response to Comment 1: The Board reviewed this comment and did not make any changes to the text based thereon. The Board does not agree that tabulating losses over a one-year time frame is burdensome. The log could be a simple excel spreadsheet or even pen and paper. Additionally, a large portion of pharmacies use a perpetual inventory system to track medication supply. Based on the needs of the pharmacy, as determined by the pharmacy, something similar could be utilized. Again, the pharmacy would need to review their processes and develop a system that meets their needs. Further, the Board notes that the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis as the aggregate total will otherwise be available to the Board through their own review of the reports. For example, as quarterly inventory counts are required by CCR

1715.65, the licensee could report any losses identified, even those under the threshold, every quarter and not have to maintain the aggregate count because the loss has been reported.

Comment 2: The commenter recommends that subsection 1715.6(a)(1)(A) – 1715.6(a)(1)(C) be amended as follows: (Commenters recommendations are in double underline for additions/double strikeout for deleted language).

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, 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 non-solid oral medication, 20 (twenty) or more ~~99~~ dosage units.

(B) For single-dose injectable medications, lozenges, film, ~~such as oral~~, buccal and sublingual, suppositories, or patches, 10 (ten) or more dosage units.

(C) For injectable multi-dose medications, medications administered by ~~continuous~~ infusion, or any other ~~multi-dose unit~~ medication not described in subparagraph (A) or (B), five ~~two~~ or more multi-dose vials, infusion bags, or other containers.

Commenter believes that the recommended reporting amounts would ensure timely reporting of "concerning losses."

Response to Comment 2: The Board reviewed this comment and did not make any changes to the text based thereon. As mentioned in the comment above, the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis. For example, as quarterly inventory counts are required by CCR 1715.65, the licensee could report any losses identified, even those under the threshold, every quarter and not have to maintain the aggregate count because the loss has been reported. A review of the underlying data within the record shows that the language reflects deliberate choices based on Board member discussion at several Board and Committee meetings.

Comment 3: Commenter recommends that a subsection 1715.6(A)(4) be added that reads "Any loss or theft reported to the Drug Enforcement Agency (DEA)" as they feel the Board should be notified of any loss reported to the DEA.

Response to Comment 3: The Board reviewed this comment and did not make any changes to the text based thereon. The Board does not believe this addition is necessary as subdivision (a)(1)(3) identifies "Any other significant loss as determined by the pharmacist-in-charge." If the loss was determined to be significant to require reporting to the DEA, the PIC should also be submitting the report to the Board per this subdivision.

Comment 4: Commenter recommends the section 1715.65(d) be amended to remove the 14-day reporting timeframe for drug losses due to theft, diversion, or self-use to match the 30-day requirement for the report identified in CCR 1715.6(a).

Response to Comment 4: The Board reviewed this comment and did not make any changes to the text based thereon as it is outside the scope of this rulemaking, which is specific to CCR section 1715.6.

Comment 5: Commenter recommends the Business and Professions Code section 4104(c) be amended to change the reporting timeframe from 14 days to 30 days when the loss is due to a licensed employee to match the 30-day requirement for the report identified in CCR 1715.6(a).

Response to Comment 5: The Board reviewed this comment and did not make any changes to the text based thereon as it is outside the scope of this rulemaking, which is specific to CCR section 1715.6. Additionally, the Board notes that statutory language cannot be amended through the regulatory process.

Comment 6: Commenter recommends the Business and Professions Code section 4134(g) be amended to change the reporting timeframe from 14 days to 30 days when the loss is due to theft, diversion, or self-use to match the 30-day requirement for the report identified in CCR 1715.6(a).

Response to Comment 6: The Board reviewed this comment and did not make any changes to the text based thereon. As identified in the response to comment 5, this comment is outside the scope of this rulemaking and statutory language cannot be amended through the regulatory process.

Written Comments from John Gray, PharmD., Kaiser Permanente

Comment 1: Commenter recommends that subsection 1715.6(a)(1) and (2) be amended to add “from the licensed facility’s inventory.” Additionally, commenter recommends the (a)(3) be amended to add “of a controlled substance from the licensed facility’s inventory” as the licensee should not be accountable for drug losses that occurred prior to the medication arriving at the facility or after it has left the facility.

Response to Comment 1: The Board reviewed this comment and did not make any changes to the text based thereon. The Board noted that the recommended change would eliminate the reporting of drug shipments lost in transit as they would no longer be considered part of any licensee’s inventory. Drug shipments lost in transit must be reported. Reporting a drug loss to the Board does not determine accountability for the loss.

Comment 2: Commenter recommends that section 1715.6(a) be further amended to reduce the one-year reporting timeframe to the previous “90 calendar days” to facilitate more “timely discovery and reporting” of losses, as well as, encourage pharmacies to complete the required quarterly inventory.

Response to Comment 2: The Board reviewed this comment and did not make any changes to the text based thereon. As indicated in a prior comment response, the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis as the aggregate total will otherwise be available to the Board through their own review of the reports.

Comment 3: Commenter recommends that subsection 1715.6(a)(1)(A), (B), and (C) be amended to reduce the reporting quantities, specifically, reducing 99 dosage units to 25 in (A) and 10 dosage units to 5 in (B) to coincide with the reduction in the reporting timeframe to 90 days. Additionally, commenter recommends that the requirement that the drug loss be from the same NDC number be added to each subsection to clarify how multiple small losses should be combined.

Response to Comment 3: The Board reviewed this comment and did not make any changes to the text based thereon. As previously mentioned, the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis as the aggregate total will otherwise be available to the Board through their own review of the reports. Additionally, the Board previously considered determining losses based on NDCs; however, determined that the aggregate total should be based on total dosage units as reflected in the language.

As no comments were received during the 15-day comment period, the regulation was adopted by the Executive Officer per the delegation issued by the Board on December 2, 2021.