Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Reporting Drug Loss

Section Affected: Amend Section 1715.6 of Article 2 of Division 17 of Title 16, California Code Regulations

Problems Addressed

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The Board's mandate and its mission is to protect the public (Business and Professions Code (BPC) section 4001.1).

Existing pharmacy law requires the owner of a licensed facility to report any loss of controlled substances to the Board within 30 days of the discovery of the loss. The report must include the amount and strengths of the loss (16 CCR 1715.6). Additionally, existing federal law requires that registrants notify the Drug Enforcement Agency (DEA), in writing, of the theft of significant loss of any controlled substances within one business day of discovery of such loss or theft (21 Code of Federal Regulation (CFR) 1301.76(b)).

As existing state law requires that any loss of controlled substance be reported to the Board, licensed facilities are required to report losses of all sizes, including single dose losses. For example, if one tablet falls on the floor while counting out the tablets to fill a prescription, that tablet must be disposed of and is considered a loss. Therefore, the licensed facility would be required to report the loss of the single tablet. This creates an administrative burden for both the licensee and the Board to prepare, review, and document the reported loss. Additionally, this type of minimal loss reporting is not required by the DEA. Further, these types of loss reporting do not provide meaningful information for the licensee or the Board with respect to the security of controlled substances within the licensed facility.

This proposal seeks to amend 16 CCR 1715.6 to eliminate this excessive reporting and more closely align the Board's regulation with the federal regulation by providing increased clarity with respect to the quantities of controlled substance losses that must be reported to the Board. While the DEA requires the reporting of any "significant" loss, the Board determined that establishing a minimum threshold will resolve the ambiguity of the term "significant" and ensure consistency and clarity for the regulated public. Additionally, the proposal does permit additional reporting of drug losses that the pharmacist-in-charge (PIC) deems "significant," in their professional judgment, to ensure that a licensed facility can report additional losses beyond those identified within the regulation, should they wish to do so.

Most drug loss reports currently received by the Board are submitted utilizing the DEA's drug loss reporting form (DEA-106). This form provides an easy tool for licensees to complete and identify the information required by this proposal. While the Board accepts

the DEA-106 form, it is not mandatory, and licensees can report the information in a manner that works for the licensed facility.

Benefits

This proposal will more closely align the Board's regulation with the federal drug loss reporting requirement. Additionally, it will increase clarity for the regulated public by establishing a minimum drug loss reporting threshold, within regulation, which will resolve the ambiguity of the term "significant" between the federal versus state reporting requirements.

Specific Purpose of Proposed Changes and Rationale

Subdivision (a) is amended to require that the owner of the licensed facility submit a report to the Board containing specific information identified in subdivision (b) no later than 30 days after the date of discovery of a drug loss. This is in existing regulation; however, the language has been amended for increased clarity to the regulated public. The phrases "a report containing the information in subdivision (b)", "no later than", and "after the date" have been added to ensure that the regulated public has a clear understanding of what must be submitted and the timing of when the information must be submitted.

Subdivision (a)(1) is amended to read "Any loss of a controlled substance in one of the following categories on or after the same day of the previous year at equal or exceed:"

- Subdivision (a)(1)(A) adds "For tablets, capsules, or other oral medication, 99 dosage units."
- Subdivision (a)(1)(B) adds "For single-dose injectable medications, lozenges, film, such as oral, buccal, and sublingual, suppositories, or patches, 10 dosage units."
- Subdivision (a)(1)(C) adds "For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described by subparagraph (A), two or more multi-dose vials, infusion bags, or other containers."

The Board selected these products based on the common package size, possible loss reasons, and how data is recorded and reported by the Board. Tablets and capsules are commonly dispensed as 100 doses or 90 doses. As the losses are the aggregate total over the previous one year, the Board determined that a total loss of 99 doses or more needed to be reported to the Board. With respect to single-dose, lozenges, film, or patches, again, the most common and smallest package available is a box of 10 doses. The Board determined that the loss of an entire box needed to be reported. Finally, for multi-dose and infusion, since these package sizes contain multiple doses, a loss of one could possibly be due to it being misplaced; however, because there are multiple doses, a loss of 2 multi-dose vials/bags/containers, may represent a trend. The Board determined that reporting losses of 99 or more, 10 or more, and 2 or more, respectively,

will put the losses on the facility's, as well as the Board's, radar; this ensures that trends or possible issues with how substances are being handled within the facility can be identified before they result in major drug losses.

Subdivision (a)(2) adds the requirement to report any loss of controlled substance, regardless of the amount, if the loss resulted from employee theft. The Board determined that a licensed facility must report any instance of employee theft of a controlled substance no matter how small. Employee theft of controlled substances must be investigated, by Board inspectors, to ensure that no additional controlled substances have been diverted and that appropriate action can be taken against the subject employee's license to restrict their access to controlled substance in the future.

Subdivision (a)(3) adds the requirement to report all other significant loss as determined by the PIC. The Board determined that it was necessary to allow the PIC, in the PIC's professional judgment, to report losses outside of those required by the regulation. The PIC will be able to determine if a loss is significant for their pharmacy. A significant loss at one pharmacy may not be a significant loss at another pharmacy based on the amount of controlled substances dispensed by the pharmacy or by other factors specific to that pharmacy. Additionally, the Board determined that use of the term "significant" was appropriate, in this section, to align with the federal drug loss reporting requirements. Title 21, Code of Federal Regulations (CFR) section 1301.74(c) requires "registrants to notify their Drug Enforcement Administration (DEA) field office of any theft or significant loss of any controlled substance [...]. The term "significant" is not defined within the CFR as the DEA has determined that what is significant in one business may not be significant in another business and that the "individual registrants must determine if a loss is significant".

Subdivision (b) adds the requirement that all reports made under this section specify the identity, amount, and strength of each controlled substance lost and the date of the discovery of the loss for each loss being reported. The requirement to identify the amount and strength of each loss is an existing requirement; however, the requirement to identify the date of the discovery is a new requirement. Identifying the date of the loss will allow the licensee and the Board to determine if the loss is being reported timely. If drug losses are not being reported timely (no later than 30 days after the date of discovery), the licensee and the Board can take corrective steps to ensure that the licensee is reporting losses timely. The new language also clarifies that the identity of the controlled substance be reported. This is for clarity to ensure that the name of the substance is identified. Reporting a drug loss would have no meaning if the name of substance lost is not identified.

Underlying Data

1. Title 21, Code of Federal Regulations (CFR) Section 1301.76
2. Federal Register, Vol. 70, No. 155 (https://www.govinfo.gov/content/pkg/FR-2005-08-12/pdf/05-15969.pdf)
3. Relevant Meeting Materials and Minutes from Board Meeting held January 29-30, 2020

4. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held January 9, 2020
5. Relevant Meeting Materials and Minutes from Board Meeting held November 5-6, 2019
6. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held November 5, 2019
7. Relevant Meeting Materials and Minutes from Board Meeting held July 24-25, 2019
8. Relevant Meeting Materials and Minutes from Board Enforcement Committee Meeting held July 10, 2019

Business Impact

The Board made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, licensed facilities are already required to report drug losses by existing law. As detailed in the Notice, the Board has determined that this proposal will reduce the number of drug loss reports being submitted by eliminating the requirement to report "all" drug losses, as the regulation establishes a minimum threshold that is not currently specified in regulation.

Economic Impact Assessment:

The Board has determined that:

(1) this proposal will not create jobs within California;
(2) this proposal will not eliminate jobs within California;
(3) this proposal will not create new businesses within California;
(4) this proposal will not eliminate existing businesses within California;
(5) this proposal will not expand businesses currently doing business in the State of California.

Existing pharmacy law requires the owner of a licensed facility to report any loss of controlled substances to the Board within 30 days of the discovery of the loss. This proposal amends existing regulation to establish minimum thresholds for reporting, which will identify in regulation, the minimal loss reporting requirement. While the proposal does impact businesses, it will not create or eliminate jobs or businesses or expand businesses doing business in California.

The Board has determined that this regulatory proposal will not impact the health and welfare of California residents, worker safety, or the state's environment. The proposal establishes a minimum threshold for reporting drug losses not currently specified in regulation. This will eliminate the requirement to report "all" drug losses. This will reduce the quantity of drug loss reports that licensed facilities are required to submit, as they will no longer be required to report single dose losses.

Fiscal Impact Assessment:

The proposed regulations will reduce the number of licensed facilities reporting a drug loss from approximately 10,000 reports per year to 6,667 per year. According to the Board, an Associate Governmental Program Analyst (AGPA) typically takes five minutes to process each report at a cost of approximately $3 per report.

As a result, the anticipated decrease of 3,333 reports received and processed by the Board each year is anticipated to result in cost savings of approximately $10,000 per year.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

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.