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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VIII. Discussion and Consideration of Adoption of Changes to Board Adopted Regulation, 16 California Code of Regulations Section 1715.6 Related to Reporting Drug Losses to Address Comments from the Office of Administrative Law

Background:

At the January 30, 2020 Board meeting, the Board approved proposed regulation text to amend Section 1715.6 related to reporting drug losses. This proposal amends the drug loss reporting requirements to further define when drug losses must be reported and to increase clarity for the regulated public.

On September 14, 2021, the final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review. Following their review, OAL requested that the Board memorialize its policy decisions identified in the Final Statement of Reasons from the July 2021 Board meeting into the regulation text.

Specifically, OAL has requested that subsection (a)(2) be 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 provide clarity that licensed employee theft must still be reported consistent with BPC 4104.

Additionally, OAL has requested that the policy discussion regarding “significant” be memorialized within the text in subsection (a)(3). The recommended language adds: “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).

Attached following this memo is the recommended amended regulation text.

At this Meeting:

The Board will have the opportunity to discuss the changes requested by OAL and initiate a 15-day comment period as requested by OAL.

Possible 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.

**Reporting Drug
Losses
16 CCR § 1715.6
Recommended
Modified Text**

**Title 16. Board of Pharmacy
Modified Text**

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Modified changes to the proposed regulation language are shown by ~~double strikethrough~~ for deleted language and double underline 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 ~~submit report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:
- (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.