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Board of Registration in Pharmacy

Policy 2022-01: Loss or Theft of Controlled Substances

I. Purpose

This policy sets forth the procedures for Board-licensed pharmacies and wholesalers that are located in Massachusetts to report possible and confirmed losses and thefts of controlled substances to the Board of Registration in Pharmacy (“Board”).

II. Reporting Requirements

Within 7 calendar days of a controlled substance loss or theft as outlined below, the [Board’s Report of Loss of Controlled Substances](#) form must be emailed to: DHPL-OPP.ADMIN@mass.gov. Any other reporting requirements of the DEA, state, and local police must also be completed.

Required reporting of both possible and confirmed losses:

- A. All losses related to employee pilferage / diversion, no matter the quantity or schedule of the medication.
- B. All significant losses of Schedule II - V controlled substances.
- C. All significant losses of Schedule VI controlled substances that are required to be reported to the MassPAT (“Prescription Monitoring Program”).

Please see DEA Guidance regarding what constitutes a “significant loss”:

https://www.deadiversion.usdoj.gov/faq/theft_loss_faq.htm

III. Losses that are Not Reportable

Insignificant losses do not require reporting. Losses determined to be insignificant after internal investigation must be documented onsite (e.g., logbook, electronic log) and tracked for adverse trending. Adverse trends (e.g., three insignificant losses of the same drug in a 90-day period) must be reported.

Losses that result from a confirmed dispensing error do not have to be reported. However, the pharmacy must comply with all requirements of [247 CMR 15.00: Continuous Quality Improvement Program](#).

IV. Investigation

Within 21 calendar days of the initial submission, all applicable documents noted in the Appendix must be submitted.

Supersedes Policy 2018-05

Please direct any questions to: DHPL-OPP.ADMIN@mass.gov

Appendix

Documentation Requirements

A. For a confirmed loss or theft, provide the following:

1. [Board's Report of Loss of Controlled Substances](#) form with any updates.
2. [DEA Form 106](#) (if applicable).

NOTE: If a DEA Form 106 that had previously been submitted to the DEA is revised or rescinded, the revised form or statement of rescission must also be submitted to the Board. The final loss quantities on the DEA Form 106 must match the Board's *Report of Loss of Controlled Substances* form.
3. Police report (if applicable).
4. An electronic copy of any relevant security footage as well as whether footage was viewed and by whom (e.g., MOR, loss prevention personnel, etc.), and what the footage revealed. If footage was not reviewed, state the reason why. Licensees must retain video records for at least 14 days or, in the case of known or suspected theft or diversion, at least two years.
5. Reconciliation report(s) for the lost medications.
6. The internal investigation, including any applicable:
 - a. incident reports
 - b. loss prevention reports
 - c. employee statements
 - d. witness statements
7. Description of the manner in which the loss was discovered.
8. Description as to how the loss occurred (if known) and the reason why it may have occurred.
9. An attestation confirming review of on-hand inventories (e.g., perpetual inventory, etc.), DEA 222 forms (as applicable), invoices, cycle counts, biennial inventory, and inventory reports for the time period to include at least 3 months prior to the loss, as well as a description of the inventory review undertaken. The description must identify and explain any discrepancies, including any periods of non-compliance with inventory requirements, and any follow-up.
10. An attestation confirming review of all staffing schedules and identification of all staff that had access at the time of the loss, including any floating or temporary staff.
11. A statement describing any changes in operations, policies, or procedures in effect at the time of the loss.

12. A statement indicating whether all corporate and / or store policies pertaining to controlled substance ordering, receiving, accountability, and management were followed. If proper policies and procedures were not followed, provide a detailed explanation including the name and license number of each individual involved (as applicable).
13. Any corrective actions taken in response to the reported loss, including, but not limited to disciplinary actions, process improvements, and changes to policies and procedures.

B. If no reportable loss has occurred, provide a detailed description of the investigatory process that concluded there was no loss, significant or otherwise. If a DEA Form 106 that had previously been submitted to the DEA is revised or rescinded, the revised form or statement of rescission must also be submitted to the Board.