

The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
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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 <u>7 calendar days</u> of a controlled substance loss or theft as outlined below, the Board's <u>Pharmacy Loss of Controlled Substances Report (RLCS)</u> and DEA Form 106 (if applicable) must be submitted.

Any other reporting requirements of the DEA, state, and local police must also be completed.

Required reporting of both possible and confirmed losses:

- A. <u>All losses</u> 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 <u>significant</u> 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":

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.

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Losses that result from a confirmed dispensing error do not have to be reported. However, the pharmacy must comply with all requirements of <u>247 CMR 15.00</u>: Continuous Quality Improvement Program.

IV. Additional Documentation

Within <u>21 calendar days</u> of the initial submission, all applicable documents noted in the Appendix must be submitted. If needed, instructions for any next steps of a **confirmed reportable loss or theft** will be provided.

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

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Appendix

Documentation Requirements

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

- 1. Board's *Pharmacy Loss of Controlled Substances Report (RLCS)* 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 Pharmacy Loss of Controlled Substances Report (RLCS).

- 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. A statement describing any changes in operations, policies, or procedures in effect at the time of the loss.
- 10. 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).
- 11. 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.

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B. If <u>no</u> <u>reportable loss</u> has <u>occurred</u>, 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.

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