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Board of Registration in Pharmacy

Policy 2018-05: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances

I. Purpose

This policy sets forth the procedures for reporting, to the Board of Registration in Pharmacy (“Board”), possible and confirmed losses and thefts of controlled substances.

II. Reporting Requirements:

In accordance with 247 CMR 6.02(10): A pharmacy or pharmacy department shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of “Report of Theft or Loss of Controlled Substance” (DEA Form 106), within seven (7) days of such theft or significant loss and, where applicable, shall comply with the reporting requirements of the DEA, the Department and the state and local police.

A pharmacy must report:

- 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/fed_regs/rules/2005/fr0812.htm

III. Definitions

- A. **Possible Loss:** *Pharmacy believes it likely experienced a significant loss of controlled substances, but further internal investigation is required.*
- B. **Confirmed Loss:** *Pharmacy confirmed that it experienced a significant loss; pharmacy’s internal investigation is complete.*

- C. **No Loss:** *Pharmacy reported a possible loss; following the pharmacy's internal investigation, controlled substances were accounted for and it was determined that a significant loss did not occur.*

IV. Procedure for Reporting

A. Submitting Reports

All reports must be emailed to:

DHPL-OPP.ADMIN@MassMail.State.MA.US.

If the pharmacy is unable to scan documents, please email the above address for instructions.

B. Possible Loss

1. Within 7 business* days of discovering a possible loss, the pharmacy must submit an email that includes the following information:
 - a. Pharmacy Name;
 - b. Pharmacy State License Number;
 - c. Pharmacy Address (including city/town & zip code);
 - d. Manager of Record Name;
 - e. Date of Possible Loss;
 - f. Drug name(s), strength, and dosage form;
 - g. Reason for Possible Loss, if known
2. Once the pharmacy's internal investigation is complete or **within 21 days of the initial email** – whichever is sooner – the pharmacy shall submit the outcome of their investigation in accordance with the requirements defined in the applicable section (C, D, or E):

C. Confirmed Loss

1. Within 7 business days of confirming a significant loss, the pharmacy shall submit:
 - a. The Board's *Report of Loss of Controlled Substances* form;
 - b. DEA Form 106, if applicable
 - c. All documentation described Appendix I

D. No Loss

1. If no controlled substance loss is determined after the pharmacy investigation, the pharmacy must indicate such and submit a notification to the board via email

to include the same information required in Section IV.B.1 above. A detailed description of the investigatory process which concluded no reportable loss occurred shall be provided as referenced in Appendix I

2. If a pharmacy rescinds or revises a DEA Form 106 previously submitted to the DEA, the pharmacy shall provide the revised DEA Form 106, or statement of rescission, with the *Report of Loss of Controlled Substances* form.

E. Losses that are Not Reportable

1. **Insignificant Losses:** Insignificant losses do not require reporting. Losses determined to be insignificant after pharmacy investigation must be documented onsite in the pharmacy (e.g. logbook, electronic log) and tracked for adverse trending. Adverse trends (e.g. 3 insignificant losses of the same drug in a 90 day period) should be reported to the Board using the procedure in Section IV.B.
2. **Losses that result from a confirmed dispensing error:** It is not necessary to report a loss that results from a confirmed dispensing error. However, the pharmacy must comply with all requirements of 247 CMR 15.00: Continuous quality improvement program.

*Business days are defined as Monday – Friday.

Appendix I

Documentation Requirements for Theft or Loss of Controlled Substances:

A. For EACH THEFT OR SIGNIFICANT LOSS, provide a statement that includes the following:

1. The manner in which the loss was discovered and the date of discovery.
2. A description as to how the loss occurred and the reason why such may have occurred.
3. A description of the security cameras in the pharmacy, where they are located, if footage was viewed and what the footage revealed. If footage was not reviewed, state the reason it was not reviewed. State the time period security videos are saved and/or archived.
4. Any corrective actions taken by the pharmacy, including, but not limited to, disciplinary actions, process improvements, and changes to policies and procedures.
5. Contact information, including email addresses, of the manager of record and any involved loss prevention personnel.

B. For EACH THEFT OR SIGNIFICANT LOSS, submit the following materials:

1. The pharmacy's internal investigation, including incident reports, loss prevention reports, employee statements, and witnesses statements.
2. Police report (if applicable).
3. Reconciliation report(s) for the lost medication(s).
4. Interview statements of employees and witnesses regarding the loss.
5. Copy of relevant security footage.

C. For each theft or significant loss of a SCHEDULE II controlled substance:

1. Submit all information required by Sections A and B above.
2. Submit an attestation confirming reconciliation of the perpetual inventory for all Schedule II controlled substances are conducted by a pharmacist at least every 10 days. If they are not conducted at least every 10 days, please indicate why.
3. Reconcile DEA 222 forms and purchase invoices against the perpetual inventory for the 3 months prior to the loss until the present date. Include a signed statement that describes if the reconciliation revealed any further discrepancies and describe the nature of the discrepancies and follow up.

E. If the DEA 106 Form indicates the *TYPE OF LOSS* is "OTHER," the pharmacy **MUST** submit a report that includes the following:

1. An attestation confirming the pharmacy reviewed perpetual inventories, 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 shall identify any periods of non-compliance with inventory requirements. The description shall identify any discrepancies.

2. An attestation confirming the pharmacy reviewed all staffing schedules and identified all staff that had access to the pharmacy at the time of the loss, including any floating or temporary staff.
3. A statement describing any changes in operations, policies, or procedures at the time of the loss.
4. A statement of the loss as a percentage of total number of units (e.g. tablets, milliliters, etc.) of that specific medication and strength dispensed by the pharmacy per month.
5. A listing of all corporate and/or store policies pertaining to controlled substance ordering, receiving, accountability, and management along with a statement describing whether policies and procedures were followed. If proper policies and procedures were not followed, provide a detailed response explaining the breakdown including the name and license number of each individual involved.

F. Upon completion of the investigation, if it is determined that no significant loss of controlled substances occurred, provide a statement that includes the following:

1. A detailed description of the investigatory process which concluded there was no loss, no significant loss of medication(s), OR how the pharmacy can otherwise account for the medication(s) in the initial notification.