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## **Policy 16-02: REQUIREMENTS AND PROCEDURES FOR REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES TO THE BOARD OF REGISTRATION IN PHARMACY**

### **I. Purpose**

The Board of Registration in Pharmacy ("Board") adopts this policy in order to set forth guidance and procedures for reporting any suspected or confirmed reportable loss or theft of controlled substances. All prescription drugs (CII – CVI) are considered controlled substances in Massachusetts.

### **II. Requirements of Reporting**

**Within one (1) business day of SUSPECTED REPORTABLE loss of controlled substances,** the pharmacy shall report to the Board by submitting Section A of the *Report of Loss of Controlled Substances* form, located on the Board's website:  
<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/mandated-reporting-forms-.html>

**Within 30 days of submission** of Section A of the *Report of Loss of Controlled Substances* form, investigation results, police reports (if applicable) and any other related documentation must be submitted utilizing Section B of the form while including information previously entered in Section A.

Please note that once a loss has been CONFIRMED and is REPORTABLE, licensees must report the loss to the Board **within 7 days** in accordance with 247 CMR 6.02 (10).

### III. Procedure for Reporting

#### What to Report to the Board:

Loss Type	Schedule II - V Reporting Requirement	Schedule VI Reporting Requirement
Employee Pilferage / Diversion	Any loss	Any loss
Break-in	Significant loss	Significant loss of MassPAT drugs
Lost in Transit	Significant loss	Significant loss of MassPAT drugs
Customer Theft	Significant loss	Significant loss of MassPAT drugs
Armed Robbery	Significant loss	Significant loss of MassPAT drugs
Other Known Loss	Significant loss	Significant loss of MassPAT drugs
Unknown Loss	Significant loss	Significant loss of MassPAT drugs

Refer to the DEA definition of significant loss for controlled substances.

Use the same definition to report the significant loss of any Schedule VI drug that is reported to MassPAT (Prescription Monitoring Program).

**DEA guidance regarding “significant loss”:**

[https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2005/fr0812.htm](https://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0812.htm)

A. The pharmacy shall notify the Board **within one (1) business day** of suspected reportable loss of controlled substances by submitting Section A of the ***Report of Loss of Controlled Substances form*** to the Pharmacy Losses mailbox at [DHPL-OPP.ADMIN@MassMail.State.MA.US](mailto:DHPL-OPP.ADMIN@MassMail.State.MA.US)

#### What to Report to the Board (“reportable losses”):

**All losses** of any Scheduled II-VI drugs must be reported to the Board when the loss is related to employee pilferage / diversion.

**All significant losses** of Schedule II-V drugs due to break-in, lost in transit, customer theft, armed robbery or other known or unknown losses must be reported to the Board.

**All significant losses** of schedule VI medications that are required to be reported to the MassPAT (Prescription Monitoring Program) must be reported to the Board when the loss is due to break-in, lost in transit, customer theft, armed robbery or other known or unknown losses.

If the loss is initially confirmed, then you may complete and submit both Sections of the form at the same time. All losses **must** be reported through the e-mail box: ([DHPL-OPP.ADMIN@MassMail.State.MA.US](mailto:DHPL-OPP.ADMIN@MassMail.State.MA.US)). If the pharmacy is unable to scan documents, please email the above address to contact Board staff.

Please note that any time a DEA 106 form is filed with the DEA, a copy must be submitted to the Board with the *Report of Loss of Controlled Substances form*.

B. The pharmacy will receive an auto-reply with instructions for next steps, and contact information.

C. The pharmacy shall complete Section B of the *Report of Loss of Controlled Substances* form ([link here](#)) as soon as the investigation is complete or **within 30 days** of the original submission, whichever is sooner. **Please note that once a loss has been confirmed and is reportable, licensees must report the loss to the Board within 7 days in accordance with 247 CMR 6.02 (10).** If a DEA Form 106 was submitted to the DEA, a copy must be submitted to the Board with the *Report of Loss of Controlled Substances* form.

D. For **confirmed reportable loss** of controlled substances, the pharmacy must provide required documentation as referenced in Appendix I (Documentation Requirements for Theft or Loss of Controlled Substances).

E. If **no controlled substance loss** is determined after the pharmacy investigation, the pharmacy must indicate such and submit on Section B of the *Report of Loss of Controlled Substances* form.

F. If a pharmacy **rescinds or revises a DEA Form 106** that has been submitted to the DEA, the pharmacy shall provide these documents with Section B of the *Report of Loss of Controlled Substances* form.

G. If a pharmacy has an **unreportable loss**, the loss shall be documented onsite in the pharmacy (i.e. logbook, electronic log) and tracked for adverse trending. If an adverse trend (i.e. 3 losses in a 90 day period) is discovered, the loss shall be reported to the Board.

H. The FAILURE of any Massachusetts pharmacy or pharmacist to make a report required by 247 CMR to the Board within the timeframe stated in 247 CMR will be grounds for discipline under 247 CMR 10.03(q).

## **Appendix I**

### **Documentation Requirements for Theft or Loss of Controlled Substances:**

#### **A. For EACH THEFT OR 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. Corrective actions (including disciplinary actions) taken by the pharmacy, including process improvements or changes to policies and procedures.
5. Contact information, including an email address, of the manager of record and any involved loss prevention personnel.

#### **B. For EACH THEFT OR LOSS, submit the following documentation:**

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 loss of a SCHEDULE II controlled substance:**

1. Submit an attestation that 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.
2. 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.

#### **D. For a drug loss resulting from a suspected DISPENSING ERROR, provide:**

1. A statement from each individual employed by the pharmacy who was involved in the dispensing error (i.e., dispensing technician, receiving personnel, verification pharmacist, etc.).
2. A statement describing any actions taken to correct the dispensing error and result of said actions, including whether the patient was contacted.
3. A copy of the prescription front and back (if applicable).

**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 that 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 that 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, if applicable.
4. A statement of the loss as a percentage of total number of units (i.e. tablets) 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 following. If proper policies and procedures were not followed, provide a detailed response explaining what occurred including the name and license number of each individual involved.