REPORTING THEFT OR LOSS OF DANGEROUS DRUGS AND PRESCRIPTION DRUG DOCUMENTS

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To assist in the implementation of rule 4729-9-15 of the Ohio Administrative Code, the State of Ohio Board of Pharmacy has developed the following guidance document. Should you need any additional assistance, please do not hesitate to contact the Board. The most expedient way to have your questions answered will be to e-mail the Board office by visiting: www.pharmacy.ohio.gov/contact.aspx. Be sure to select "Compliance/Enforcement Information" as your subject line.

Q1: When am I required to report a theft or significant loss of dangerous drugs?

The State of Ohio Board of Pharmacy requires a licensee (pharmacist, terminal/wholesale distributor) to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to the prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs.

All licensees must comply with this requirement, and such compliance cannot be overridden by an internal corporate policy that is contrary to the Board’s notification requirement.

A corporation that owns/operates multiple registered sites and wishes to channel theft and loss notifications through a central point such as corporate loss prevention, corporate security, or other corporate entity may do so, but the licensee and its Board licensed employees must still fulfill the requirement to provide the required immediate notification.

Q2: How do I report a theft or significant loss?

Theft or loss should be reported by telephone immediately upon discovery. You may call the Board’s main line (614.466.4143) or your assigned compliance specialist or agent.

Q3: How does the Board define “immediately upon discovery”?

The Board of Pharmacy defines “upon discovery” to mean the following:
1. Upon the “reasonable suspicion” that a loss has occurred, whether the loss can be proven to be an actual theft or significant loss, or not, a report shall be made to the State of Ohio Board of Pharmacy.
2. In the context of reporting a theft or significant loss, “reasonable suspicion” means, having more than an “suspicion or hunch”, but having “specific and articulable facts” that, when taken together with rational inferences and a combination of particular facts, even if each is individually innocuous, would lead a reasonable person to believe a theft or loss has occurred.

**Q4: What is a significant loss?**

It is the responsibility of the licensee to use their professional judgment to take appropriate action. Whether a “significant loss” has occurred depends, in large part, on the licensee’s business type and the likelihood of a rational explanation for a particular occurrence. Further, the loss of a small quantity of dangerous drugs, repeated over a period of time, may indicate a significant problem, which must be reported.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of dangerous drugs lost in relation to the type of business;
2. Whether the loss of the dangerous drugs can be associated with access to those drugs by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the dangerous drugs;
3. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
4. Whether the specific dangerous drugs are likely candidates for diversion; and
5. Local trends and other indicators of the diversion potential of the missing dangerous drugs.

**Q5: What are the additional requirements for reporting theft or significant loss of controlled substances?**

If a controlled substance is involved, the Drug Enforcement Administration (DEA) must also be notified online using the DEA Form 106. This form can be found on the DEA website: [https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp](https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp).

This form must also be submitted to the board within 30 days following the discovery of a controlled substance theft or significant loss. The form may be emailed (DEA106Reporting@pharmacy.ohio.gov) or faxed (614.752.4836).

More information about DEA reporting requirements can be found here: [http://www.deadiversion.usdoj.gov/21cfr_reports/theft/](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/)
Q6: What are the reporting requirements for the theft or loss of prescription drug documents?

Each prescriber, terminal distributor of dangerous drugs or wholesale distributor of dangerous drugs must notify the Board of Pharmacy immediately upon discovery of any theft or loss of any of the following:

1. Uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed.

2. Official written order form(s) as defined in division (Q) of section 3719.01\(^1\) of the Revised Code.

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\(^1\) "Official written order" means an order written on a form provided for that purpose by the director of the United States drug enforcement administration, under any laws of the United States making provision for the order, if the order forms are authorized and required by federal law.