



Reporting Theft or Loss of Dangerous Drugs and Drug Documents

Updated 2/4/2019

Effective March 1, 2019, rules 4729:5-3-02 and 4729:6-3-02 require terminal distributors and drug distributors (manufacturers, wholesalers, third-party logistics providers, repackagers and outsourcing facilities) to report theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents via the Board's [online portal](#). A guidance document for submitting information through the portal is available here: www.pharmacy.ohio.gov/reportTL.

Copies of the rules are included at the end of this document.

For more information on the implementation of these rules, please review the following frequently asked questions and the rule text included at the end of this document.

NOTE: The online portal is now operational and may be used to meet current theft or significant loss notification and reporting requirements in accordance with rule [4729-9-15 of the Ohio Administrative Code](#). The current rule will be rescinded effective March 1, 2019.

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?

Rules 4729:5-3-02 and 4729:6-3-02 of the Ohio Administrative Code require a licensee (terminal distributor and drug 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 a prescriber, terminal distributor, or drug distributor.

IMPORTANT: For laboratories and other licensees that may possess controlled substances that are not prescriptions drugs (i.e. testing standards, controlled substances



for dog training, etc.) this reporting requirement also applies.

In addition, the licensee must also contact local law enforcement and, if the theft or significant loss involves controlled substances (and the licensee holds a DEA registration), the Drug Enforcement Administration (DEA) immediately upon the discovery of a theft or significant loss. More information about DEA notification requirements can be found here: https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

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 licensed 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 must still provide the required immediate notification.

Q2: How do I immediately notify the Board of Pharmacy upon discovery of a theft or significant loss?

Theft or significant loss must be reported **immediately upon discovery** using either of the following methods:

1. Via the Board's [online portal](#). A guidance document for submitting information through the portal is available here: www.pharmacy.ohio.gov/reportTL. (**NOTE:** While not required to use the online portal for immediate notification, the Board strongly encourages a licensee to utilize this option).

-OR-

2. You may call the Board's main line (614.466.4143) and ask to speak with the Compliance and Enforcement Department or your assigned compliance specialist, inspector or agent.

Q3: How does the Board define 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 Board of Pharmacy.

2. In the context of reporting a theft or significant loss, “reasonable suspicion” means, having more than a “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 significant 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 drugs, repeated over a period of time, may indicate a significant problem, which must be reported.

When determining whether a loss is significant, a licensee 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.

IMPORTANT: The loss of **any** Schedule I controlled substances and the following controlled substance drugs must be treated as a significant loss and reported immediately:

- Thiafentanil
- Carfentanil
- Etorphine hydrochloride
- Diprenorphine

Q5: What are the additional requirements for reporting theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs)?

In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or significant loss to the Board using the [online portal](#) **within thirty days** following the discovery of such theft or significant loss. This detailed report is

similar to the form required by DEA ([Form 106](#)) and **must** be submitted using the online portal.

A guidance document for submitting information through the portal is available here: www.pharmacy.ohio.gov/reportTL

IMPORTANT: The report must be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

An exemption to the thirty-day reporting timeframe may be obtained upon sufficient cause if the report cannot be filed within thirty days. To obtain an exemption, the licensee must submit a request to the Board by email (dea106reporting@pharmacy.ohio.gov) that includes all the following information:

- Licensee name and address;
- License number;
- Contact person name and phone number;
- A detailed justification as to why the required information cannot be submitted to the Board within the required timeframe; and
- The requested extension date for submission of the report.

If a controlled substance is involved and the licensee is a DEA registrant, the DEA must also be notified and a DEA Form 106 form must be submitted. More information about DEA notification requirements can be found here:

https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

Q6: What are the reporting requirements for the theft or loss of drug documents?

Drug documents include any of the following:

1. Uncompleted prescription blank(s) used for writing a prescription;
2. Written prescription order(s) not yet dispensed;
3. Original prescription order(s) that have been dispensed; or
4. DEA controlled substance order forms ([DEA Form 222](#)).

IMPORTANT: Unlike dangerous drugs, **any theft or loss** of drug documents must be reported to the Board immediately upon discovery.

For 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:

A licensee is required to report, **immediately upon discovery**, to the Board and law enforcement authorities **any theft or loss** of 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.

Theft or loss **must** be reported to the Board via the [online portal](#). A guidance document for submitting information through the portal is available here: www.pharmacy.ohio.gov/reportTL.

NOTE: Unlike dangerous drugs, a licensee is not required to submit a detailed follow-up report within thirty days of the initial report of theft or loss of drug documents.

For DEA controlled substance order forms (DEA Form 222):

A licensee is required to report, **immediately upon discovery**, to the Board, local law enforcement authorities and the DEA any theft or loss of used or unused DEA 222 Forms.

Theft or loss must be reported to the Board via the [online portal](#). A guidance document for submitting information through the portal is available here: www.pharmacy.ohio.gov/reportTL.

NOTE: Unlike dangerous drugs, a licensee is not required to submit a detailed follow-up report within thirty days of the initial report of theft or loss of drug documents.

For more information on the DEA theft or loss reporting of DEA 222 Forms, visit: https://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_16.htm

Q7: I am a virtual wholesaler and utilize a third-party logistics provider (3PL) to ship drug stock, which licensee is required to report a theft or significant loss?

As the facility that physically possesses the drugs, the 3PL would be responsible for filing the theft or significant loss report with the Board.

Q8: What are the requirements for reporting out-of-state theft or losses?

Theft or significant losses should only be reported by the following:

1. Licensees physically located in Ohio (regardless of where the drugs are being shipped); and
2. Out-of-state licensees but only for drugs being shipped into the state.

Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.

- (A) A person licensed in accordance with section 4729.52 of the revised code or this division of the administrative code shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:
- (1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;
 - (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (1/21/2016);
 - (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.
- (B) The theft or significant loss of controlled substances by a licensee shall be reported by using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss.
- (1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.
 - (2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.
- (C) The theft or significant loss of non-controlled dangerous drugs shall be reported by a licensee to the state board of pharmacy, in a manner determined by the board, within thirty days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.
- (1) An exemption may be obtained upon sufficient cause if the form cannot be filed within thirty days.
 - (2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.
- (D) A person licensed in accordance with section 4729.52 of the revised code or this division of the administrative code shall, immediately upon discovery, notify the

state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of 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.

(E) A person licensed in accordance with section 4729.52 of the revised code or this division of the administrative code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.12 (1/21/2016) of the theft or loss of any official written order form(s) as defined in division (Q) of section 3719.01 of the Revised Code.

Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.

(A) A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;

(2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (1/21/2016);

(3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

(B) The theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported to the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

(D) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of 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.

(E) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.12 (1/21/2016) of the theft or loss of any official written order form(s) as defined in division (Q) of section 3719.01 of the Revised Code.