5/30/2017

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

Rescinded

- 4729-9-06: Provides the requirements for the destruction of controlled substances by a terminal and wholesale distributor of dangerous drugs. Rule content is being moved to newly created divisions in the OAC.
- 4729-9-15: Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs. Rule content is being moved to newly created divisions in the OAC.

New

- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs.
- 4729:5-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs.
- 4729:6-3-01 – Provides the requirements for the destruction of controlled substances by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs.
- 4729:6-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs.

Comments on the proposed rules will be accepted until close of business on June 14, 2017. Please send all comments to the following email address:
Cameron.mcnamee@pharmacy.ohio.gov

In addition, please copy your comments to:
CSIPublicComments@governor.ohio.gov

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Drug destruction; reporting theft or loss

Rule Number(s): Rescinded: 4729-9-06; 4729-9-15

New: 4729:5-3-01; 4729:5-3-03; 4729:6-3-03; 4729:6-3-01

Date: 5/30/2017

Rule Type:

New	5-Year Review
Amended	**Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Rescinded

- 4729-9-06: Provides the requirements for the destruction of controlled substances by a terminal and wholesale distributor of dangerous drugs. Rule content is being moved to newly created divisions in the OAC.
- 4729-9-15: Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs. Rule content is being moved to newly created divisions in the OAC.

New

- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs.
- 4729:5-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs.
- 4729:6-3-01 – Provides the requirements for the destruction of controlled substances by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs.
- 4729:6-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

Both rules require adherence to federal rules regarding theft/loss and controlled substance drug destruction.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule package exceeds federal requirements because the regulation of dangerous drugs (including non-controlled drugs) has been granted by the Ohio legislature to the State of Ohio Board of Pharmacy. The regulation ensures clear requirements for the destruction of controlled substances and the reporting of theft or significant loss of both controlled and non-controlled substances by Ohio licensees.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules regarding the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

The content of the rules in this package were reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year review date.

The content of the rules was also reviewed and approved by the Board of Pharmacy.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed content of the rules. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

Scientific data was not used to develop or review this rule but federal standards regarding what constitutes controlled substance destruction were utilized.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for controlled substance destruction as well as consistent reporting of theft or significant loss of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform regulations across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Long-term care facilities;
- Terminal distributors of dangerous drugs; and
- Wholesale distributors of dangerous drugs, manufacturers of dangerous drugs, outsourcing facilities, third-party logistics providers and repackagers of dangerous drugs.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Violation of these rules may result in administrative licensure discipline for a licensee. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

Rescinded

- 4729-9-06: Provides the requirements for the destruction of controlled substances by a terminal and wholesale distributor of dangerous drugs. Rule content is being moved to newly created divisions in the OAC. No adverse impact expected by rescinding this regulation.
- 4729-9-15: Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs. Rule content is being moved to newly created divisions in the OAC. No adverse impact expected by rescinding this regulation.

Amended

- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs. Directors of nursing and nurses employed at long term care facilities must complete a proof of use sheet and be present for any transfer or destruction of controlled substances. Requires maintaining of all destruction records for three years and complying with all federal destruction requirements, including

utilization of a method that renders controlled substances "non-retrievable". It should be noted that maintaining records pertaining to controlled substances for three years is required by the Ohio Revised Code (3719.07).

- 4729:5-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs. A licensee must report theft or significant loss of a dangerous drug immediately by phone and complete a form within thirty days. The theft or significant loss form can take about 30 minutes to complete.
- 4729:6-3-01 – Provides the requirements for the destruction of controlled substances by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs. Requires maintaining destruction records for three years and complying with all federal destruction requirements, including utilization of a method that renders controlled substances "non-retrievable". It should be noted that maintaining records pertaining to controlled substances for three years is required by the Ohio Revised Code (3719.07).
- 4729:6-3-03 – Provides the requirements for reporting the theft or loss of dangerous drugs by a wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs. A licensee must report theft or significant loss of a dangerous drug immediately by phone and complete a form within thirty days. The theft or significant loss form can take about 30 minutes to complete.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform drug destruction standards. In addition, they support efforts to accurately report the theft or significant loss of both controlled and non-controlled dangerous drugs.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of drug destruction or the reporting of theft or significant loss is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-9-06 Disposal of dangerous drugs which are controlled substances. (RESCIND)

(A) As used in this rule, "non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(B) Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.

(C) If a pharmacy is servicing a long term care facility or a consultant pharmacist is employed by a long term care facility and is having a pharmacist witness the destruction of ultimate user (patient-owned) controlled substances in the custodial care of nursing staff in an inpatient setting, then the pharmacy or consultant pharmacist shall have policies and procedures in place to ensure compliance with and shall comply with all of the following:

(1) Upon discontinuation of a patient's controlled substance medication, a nurse and director of nursing, or other pharmacy-approved supervisory nurse, must document the removal of the patient's medication from the medication cart or storage area and record the transfer of the medications to a secure storage area for disposal.

(2) The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on the required controlled substance proof-of-use sheet pursuant to rule 4729-17-05 of the Administrative Code. Records shall contain the date, patient name, drug name, drug strength, quantity, and the positive identification of the two nurses responsible for removing the medications from the medication cart, or other storage area, and transferring the medications into the secure storage area.

(3) An Ohio licensed pharmacist and the director of nursing, or other pharmacy or pharmacist approved supervisory level nurse, may destroy ultimate user (patient owned) controlled

substances using an on-site method. Both individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (C)(4) of this rule. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

(4) A record of controlled substances destroyed shall be made, containing the date of destruction, patient name, drug name, drug strength, quantity, method of destruction and the positive identification of the Ohio licensed pharmacist and the director of nursing, or other pharmacy or pharmacist approved supervisory level nurse, responsible for the destruction.

(5) The record of controlled substance destruction pursuant to paragraph (C)(4) of this rule shall be maintained on-site for a minimum of three years and made available to the board of pharmacy upon request.

(D) The unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply may be destroyed using an on-site method by any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable. A record of such destruction shall be made in accordance with 21 C.F.R. 1304 (1/1/2016) and shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.

4729-9-15 Report of theft or loss of dangerous drugs, controlled substances, and drug documents. (RESCIND)

(A) Each prescriber, terminal distributor of dangerous drugs, or wholesale 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 prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs:

(1) The state board of pharmacy, by telephone 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(b) (1/21/2016);

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

(B) Controlled substance thefts must also be reported by using the federal DEA report form whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the state board of pharmacy within thirty days following the discovery of such theft or 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 writing.

(C) Each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs immediately upon discovery of any theft or loss of:

(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, shall notify the state board of pharmacy and law enforcement authorities.

(2) Official written order form(s) as defined in division (Q) of section 3719.01 of the Revised Code shall notify the state board of pharmacy and law enforcement authorities, and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.12(b) (1/21/2016).

4729:5-3-01 Disposal of controlled substances (NEW).

(A) As used in this rule:

(1) “Controlled substance proof-of-use sheet” means a record utilized by a long-term care facility that captures, at a minimum, the following information:

(a) Date;

(b) Patient name;

(c) Drug name;

(d) Drug strength;

(e) Quantity; and

(f) The positive identification of the two nurses, licensed in accordance with Chapter 4723. of the Revised Code, responsible for removing the dangerous drugs from the medication cart, or other storage area, and transferring the drugs to the secure storage area.

(2) "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(B) A terminal distributor of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.

(1) If a long-term care facility uses a method of destruction pursuant to 21 C.F.R. 1317 (1/1/2016), the controlled substances transferred to a collection receptacle or mail-back envelope must be completed by the director of nursing and witnessed by nurse licensed in accordance with Chapter 4723. of the Revised Code. The amount of drug transferred to the receptacle or mail-

back envelope and the method of disposal used must be documented with the positive identification of both individuals on the corresponding controlled substance proof-of-use sheet.

(C) If a pharmacy is servicing a long-term care facility or a consultant pharmacist is employed by a long-term care facility and is having a pharmacist witness the destruction of ultimate user (i.e. patient-owned) controlled substances in the custodial care of nursing staff, the pharmacy or consultant pharmacist shall have policies and procedures in place to ensure compliance with and shall comply with all the following:

(1) Upon discontinuation of a patient's controlled substance medication, a nurse and director of nursing, or other pharmacy-approved supervisory nurse, must document the removal of the patient's dangerous drugs from the medication cart or storage area and record the transfer of the drugs to a secure storage area for disposal.

(2) The record of the controlled substances removed from the medication cart, or other area of storage, for disposal shall be made on a controlled substance proof-of-use sheet.

(3) An Ohio licensed pharmacist and the director of nursing, or other pharmacy-approved supervisory level nurse, may destroy ultimate user controlled substances using an on-site method. Both individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (C)(4) of this rule. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

(4) A record of controlled substances destroyed shall be made, containing the date of destruction, patient name, drug name, drug strength, quantity, method of destruction and the positive identification of the Ohio licensed pharmacist and the director of nursing, or other pharmacy approved supervisory level nurse, responsible for the destruction.

(5) The record of controlled substance destruction pursuant to paragraph (C)(4) of this rule shall be maintained on-site for a minimum of three years and made available to the board of pharmacy upon request.

(D) The unused portion of a controlled substance resulting from administration to a patient from a licensee’s stock or emergency supply may be destroyed using an on-site method by any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess controlled substance dangerous drugs. The on-site method does not have to meet the definition of non-retrievable but must render the drug unavailable and unusable. A record of such destruction shall be made in accordance with 21 C.F.R. 1304 (1/1/2016) and shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.

4729:5-3-03 Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (NEW)

(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 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) A theft or significant loss of non-controlled dangerous drugs report form 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 of non-controlled dangerous drugs. The form 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.

4729:6-3-01 Disposal of controlled substances (NEW).

(A) As used in this rule:

(1) "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

(B) A wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (1/1/2016). The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the board of pharmacy upon request.

4729:6-3-03 Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (NEW)

(A) A wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager 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 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) A theft or significant loss of non-controlled dangerous drugs report form 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 of non-controlled dangerous drugs. The form 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 wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager 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 wholesale distributor of dangerous drugs, manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider and repackager 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.