4/09/15

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 Ohio State 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.

New Rule

- **4729-5-28:** Formalizes a Board policy that was adopted in 2007 into administrative rule regarding the requirements for an approved remote order entry system.

Amended Rules

- **4729-5-20:** Revises the drug utilization review process regarding pharmacist use of the Ohio Automated Rx Reporting System (OARRS).
- **4729-9-12:** Clarifies a recent change in the ORC that requires certain prescriber businesses that were exempt from terminal distributor of dangerous drugs licensure to become licensed if they possess certain drugs on-site. Also, requires TDDD to check the status of entities if they are providing compounded drugs for in-office administration pursuant to a new OAC section that will be effective on May 1st.
- **4729-9-08:** Requires a terminal or wholesale distributor to submit a new application within 30 days of any change in the ownership, business or trade name, category or address of the distributor.
- **4729-9-15:** Updates the process for reporting the theft or loss of dangerous drugs or official written prescription order form.

Comments on the proposed rules will be accepted until close of business on April 24, 2015. Please send all comments to the following email address:
Cameron.mcnamee@bop.ohio.gov

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Pharmacists & Dangerous Drugs

Rule Number(s): New: 4729-5-28

Amended: 4729-5-20; 4729-5-28; 4729-9-12; 4729-9-08; 4729-9-15

Date: 04/09/2015

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Amended	Rescinded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.

New Rule

- **4729-5-28:** Formalizes a Board policy that was adopted in 2007 into administrative rule regarding the requirements for an approved remote order entry system.

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- **4729-9-12:** Clarifies a recent change in the ORC that requires certain prescriber businesses that were exempt from terminal distributor of dangerous drugs (TDDD) licensure to become licensed if they possess certain drugs on-site. Also, requires TDDD to check the status of entities if they are providing compounded drugs for in-office administration pursuant to a new OAC section that will be effective on May 1st.
- **4729-9-08:** Requires a terminal or wholesale distributor to submit a new application within 30 days of any change in the ownership, business or trade name, category or address of the distributor.
- **4729-9-15:** Updates the process for reporting the theft or loss of dangerous drugs or official written prescription order form.

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. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 3719.04, 4729.51, 4729.54, 4729.541 and 4729.60.

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?

The rule does not implement a federal requirement.

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 the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice and oversight of locations where dangerous drugs are stored. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy traditionally has been left to state boards.

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 state board of pharmacy to adopt rules governing the practice of pharmacy, which includes a pharmacist's scope of practice and the regulation of entities that store dangerous drugs.

Section 3719.28 of the Ohio Revised Code requires the state board of pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and 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.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapters 4729 and 3719 of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide uniform standards for the review of patient data in the Ohio Automated Rx Reporting System.
- Provide uniform regulations regarding the approval of remote order entry systems.
- Provide a standard system for the reporting of lost or stolen dangerous drugs and official written prescription orders.
- Ensure that entities that sell dangerous drugs verify that a purchaser is properly licensed to possess those drugs.
- Ensure that locations that are licensed to store dangerous drugs report any changes to the Board within a timely manner.

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 and prescribers of dangerous drugs 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 rules were reviewed and approved by the Ohio State Board of Pharmacy's Rules Review Committee on February 20, 2015. The committee is comprised of a broad array of stakeholders including:

- Select Specialty Hospital – Akron
- Berger Health System
- The Kroger Company
- Meijer
- Nationwide Children's Hospital
- Fort Hamilton Hospital
- Central Ohio Compounding Pharmacy
- Healthspan Physicians and Integrated Care
- Cedarville University School of Pharmacy
- Fairview Hospital – Cleveland Clinic
- OhioHealth
- Wal-Mart
- Pharmacy Systems, Inc.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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 Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback from the committee 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 the rule.

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 rules and prompt reporting by locations that store dangerous drugs, the Ohio State 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 Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Chief Counsel and Pharmacist Compliance Supervisor reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio State 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 rule will be posted on the Pharmacy Board's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board 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, monthly email updates from the director of policy and communications as well as feedback from the Board's legal counsel 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:

- Ohio licensed Pharmacists;
- Locations licensed as Terminal Distributors of Dangerous Drugs; and
- Locations licensed as Wholesale Distributors 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 pharmacist, wholesale distributor of dangerous drugs or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- **4729-5-28:** Formalizes a Board policy that was adopted in 2007 into administrative rule regarding the requirements for an approved remote order entry system. This policy has been in place for a number of years for any entity wishing to implement a remote order entry system. Formalizing this process into rule should not result in any adverse impact.
- **4729-5-20:** Revises the drug utilization review process regarding pharmacist use of the Ohio Automated Rx Reporting System (OARRS). This rule includes additional requirements for pharmacists for checking OARRS when presented with controlled substance prescriptions. As such, this will result in increased administrative costs for pharmacies that provide outpatient controlled substance prescriptions. The average time to run an OARRS report is approximately 90-120 seconds.
- **4729-9-12:** Clarifies a recent change in the ORC that requires certain prescriber businesses that were exempt from terminal distributor of dangerous drugs (TDDD) licensure to become licensed if they possess certain drugs on-site. Also, requires TDDD to check the status of entities if they are providing compounded drugs for in-office administration pursuant to a new OAC section that will be effective on May 1st. This will result in increased administrative costs for pharmacies to verify that a site is properly licensed to possess compounded drugs. Verification would take approximately 1 minute by querying the entity placing the order via the state's e-licensing system.
- **4729-9-08:** Requires a terminal or wholesale distributor to submit a new application within 30 days of any change in the ownership, business or trade name, category or address of the distributor. This rule simply specifies the timeframe that an entity must submit a new application upon the aforementioned changes. As such, it should not result in any increased costs to a licensee. However, this rule does require a new application which takes approximately one hour to complete and requires a fee of $112.50 - $150 for terminal distributors and $750 - $787.50 for wholesale distributors.

- **4729-9-15:** Updates the process for reporting the theft or loss of dangerous drugs or official written prescription order form. This rule still requires the reporting of any loss or theft however it allows for a convenient online form that can be submitted rather than a telephone call during normal business hours. Therefore, this rule should not result in any increased administrative costs.

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

The Ohio State Board of Pharmacy believes that the regulatory intent of the proposed rules is necessary in order to protect the health and safety of all Ohioans by providing uniform regulations to ensure the following:

- Consistent standards for reviewing OARRS by a pharmacist;
- Consistent standards to be followed by terminal distributors when selling compounded dangerous drugs to prescriber offices within the State of Ohio.
- Consistent requirements for notifying the board of any changes to licensed locations that store dangerous drugs;
- Clear understanding of what constitutes an approved remote order entry system; and
- Clear reporting requirements for the theft or loss of 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 Ohio State 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 pharmacy 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, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-5-20 Prospective drug utilization review.

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment;

(9) Food-nutritional supplements-drug interactions.

(B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's report, pursuant to paragraph (D) of this rule, ~~if applicable and available,~~ and/or consulting with the prescriber and/or counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information;

(3) United States pharmacopoeia drug information;

(4) American medical association evaluations.

~~(D) Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one-year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person currently:~~

~~(1) Receiving reported drugs from multiple prescribers;~~

~~(2) Receiving reported drugs for more than twelve consecutive weeks;~~

~~(3) Abusing or misusing reported drugs (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);~~

~~(4) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or.~~

~~(5) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.~~

~~After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.~~

~~In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.~~

(D)(1) Prior to dispensing an outpatient prescription for a reported drug as listed in rule 4729-37-02 of the Ohio Administrative Code, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period, including a border state's information when the pharmacist is practicing in a county bordering another state if that state's information is available, in any of the following circumstances:

(a) A patient adds a different or new reported drug to their therapy that was not previously included;

(b) An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile;

(c) A prescriber is located outside the usual pharmacy geographic area;

(d) A patient is from outside the usual pharmacy geographic area;

(e) A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months, unless the prescriptions are from prescribers who practice at the same physical location;

(f) Patient is exhibiting signs of potential abuse or diversion~~, or over-utilization of any dangerous drug~~. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or

intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.

(2) In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

(3) A pharmacist may use a delegate to request an OARRS report.

(E) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. Based upon information obtained during prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist is not required to dispense a prescription of doubtful, questionable, or suspicious origin.

4729-9-12 Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.

(A) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code.

(1) The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs. If the certificate of license indicates a limited category I, II, or III license, the terminal distributor shall furnish the wholesale distributor a copy of the current license addendum listing those drugs the purchaser is authorized to possess.

(2) If no certificate of license as a terminal distributor is obtained or furnished before the sale, both the seller and the purchaser shall be considered to be in violation of section 4729.60 of the Revised Code.

(B) Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code.

(1) The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs.

(2) If no registration number of the wholesale distributor is obtained or furnished before the purchase, both the purchaser and the seller shall be considered to be in violation of section 4729.60 of the Revised Code.

(C) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a prescriber as defined in division (I) of section 4729.01 of the Revised Code, the wholesale distributor must obtain:

(1) A copy of the current certificate of license as a terminal distributor from the prescriber pursuant to division (A) of section 4729.60 of the Revised Code and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or

(2) Unless the prescriber meets the terminal distributor of dangerous drugs licensing requirements in section 4729.541 of the Revised Code, copies of all documents required to establish that the prescriber is exempt from licensure as a terminal distributor of dangerous drugs pursuant to divisions (B)(1)(a), (B)(1)(j), and (B)(1)(k) of section 4729.51 of the Revised Code and is authorized by federal and state laws to purchase the dangerous drugs for use in the course of his/her professional practice. The required documents are as follows:

(a) An individual prescriber doing business as a sole proprietor (not incorporated in any manner) as set forth in division (B)(1)(a) of 4729.51 of the Revised Code, an individual prescriber doing business as a sole shareholder of a corporation or a limited liability company pursuant to division (B)(1)(j) of section 4729.51 of the Revised Code, and a dentist pursuant to division (B)(1)(k) of 4729.51 of the Revised Code must provide a copy of his/her current license to practice and the license must authorize the use of the drugs requested from the wholesaler in his/her practice. Also, a prescriber doing business as a sole shareholder of a corporation or a limited liability company must also provide official documentation that states he/she is the sole shareholder;

(b) The address of all sites of practice where the drugs will be delivered to and stored for use by the prescriber in his/her professional practice pursuant to federal and state laws;

(c) Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the wholesaler and maintained by the wholesaler with all other documents establishing the prescriber's exemption from licensure as a terminal distributor of dangerous drugs;

(d) If an exempted prescriber wishes to purchase and possess dangerous drugs which are also controlled substances, the prescriber must submit a copy of his/her current registration with the federal drug enforcement administration and provide verification that the DEA registration and authority to use controlled substances in the course of professional practice has not been restricted by the appropriate professional licensing board or the federal drug enforcement administration.

(D) Dangerous drugs may not be shipped by a wholesale distributor of dangerous drugs to any address other than those listed by the business entity meeting the definition of a prescriber and filed with the wholesale distributor in paragraph (B) of this rule. Controlled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances.

(E) All documents establishing the fact that a prescriber is exempt from licensure as a terminal distributor of dangerous drugs shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.

(F) Copies of licenses to practice and verification that there are no restrictions on a prescriber's license by either the appropriate professional licensing board or the federal drug enforcement administration shall be obtained within fifteen days of the date of renewal of such licenses. No dangerous drugs may be sold and delivered to a prescriber until the required documentation has been obtained by the wholesale distributor.

(G) Each wholesale distributor of dangerous drugs registered with the state board of pharmacy shall report any suspicious purchases of any dangerous drugs by a prescriber exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the prescriber is not authorized to use in the course of his/her professional practice.

(H) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729-16-07 of the Administrative Code, the terminal distributor of dangerous drugs must confirm a current certificate of license as a terminal distributor from the purchaser.

4729-5-28 Remote Pharmacy Computer Access

(A) To be considered board-approved for remote pharmacy computer access, the following requirements, at a minimum, shall be met:

(1) The remote computer shall have positive identification, pursuant to rule 4729- 5-01(N), of the pharmacist accessing the computer system. If an alternative method to achieve positive identification is desired, it shall be presented to the board for approval.

(2) The remote computer access shall only involve pharmacists and they shall be licensed in Ohio. If not, the procedure for remote pharmacy computer access shall be presented to the Board for approval.

(3) There shall be an audit trail of any pharmacist remotely accessing the pharmacy computer system. The audit information shall contain at least the date, time, information reviewed, information entered, and pharmacist accessing the system. This information shall be placed in a report that is reviewed and compared to the orders/documentation as soon as possible by the Responsible Pharmacist or his/her designee. A policy shall be in place to detail this quality assurance procedure.

(4) The remote access and order information received shall be secure to ensure confidentiality. The pharmacy shall have a confidentiality policy and make a reasonable attempt to determine that it is being followed. If appropriate, this may require a site inspection by the Responsible Pharmacist or his/her designee.

(5) The Board shall inspect and approve remote pharmacy computer access and its policies prior to use.

4729-9-08 Change in description of terminal or wholesale dangerous drug facility.

For the purpose of division (E) of section 4729.51 and division (D) of section 4729.52 of the Revised Code, any change in the ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within 30 days of any change in the ownership, business or trade name, category, or address.

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

(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~~ through an online form available on the board's web site (www.pharmacy.ohio.gov), within three business days upon discovery of the theft or significant loss; and

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

~~(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) .~~

(B) Each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs shall notify the state board of pharmacy, through an online form available on

the board's web site (www.pharmacy.ohio.gov), within three business days upon discovery of the theft or loss of any of the following:

(1) Uncompleted prescription blank(s) used for writing a prescription;

(2) Written prescription order(s) not yet dispensed; and

(3) Original prescription order(s) that have been dispensed.

(C) Each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs shall notify the following upon discovery 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:

(1) The state board of pharmacy, through an online form available on the board's web site (www.pharmacy.ohio.gov), within three business days upon discovery of the theft or loss; and

(2) The drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.12(b).