3/06/2018

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.

Amended

- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs. Amended to extend the destruction date of dangerous drugs by a long-term care facility to ten days.

Comments on the proposed rules will be accepted until close of business on **March 28, 2018**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

In addition, please copy your comments to: **CSIPublicComments@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; long-term care facility

Rule Number(s):

Amended:

- **4729:5-3-01**

Date: 3/6/2018

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Amended	Rescinded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.**

Amended

- 4729:5-3-01 – Provides the requirements for the destruction of controlled substances by a terminal distributor of dangerous drugs. Amended to extend the destruction date of dangerous drugs by a long-term care facility from five to ten days.

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

The proposed rule is 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?**

The amended rule require adherence to federal rules regarding 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 exceeds federal requirements because the regulation of dangerous drugs has been granted by the Ohio General Assembly to the State of Ohio Board of Pharmacy. The regulation ensures clear requirements for the destruction of 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 prescribing 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.

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

The success of the regulation 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 rule.

Development of the Regulation

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

The rule was reviewed by stakeholders including the American Society of Consultant Pharmacists, Ohio Chapter of the American Society of Consultant Pharmacists, and pharmacists from the long-term care and consultant pharmacy practice setting.

Prior to filing with CSI, the amended rule was 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?

The rule is being amended after concerns were raised by stakeholders that had not been raised during the initial rule-making process. Board staff held a conference call with impacted stakeholders and brought the concern to the Board of Pharmacy. The Board approved the amendment of the rule to allow for discontinued controlled substances to be disposed of within ten days (up from five days as currently stated).

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.

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 the practice of pharmacy and distribution 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 practice standards 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 rule 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 rule 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:

- Pharmacies servicing long-term care facilities licensed as terminal distributor of dangerous drugs.

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

Violation of this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. 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.

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. Requirements 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). The rule is being amended to extend the destruction date of dangerous drugs by a long-term care facility from five to ten days. According to stakeholders, this should ease the regulatory burden of the rule.

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 to prevent diversion.

Regulatory Flexibility

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

This rule does 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 pharmacy or the disposal of dangerous drugs 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 and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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

(A) As used in this rule:

(1) "Controlled substance proof-of-use sheet" means a record 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, as defined in agency 4729. of the Administrative Code, of the individuals authorized by this rule who are 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 readily retrievable 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 a nurse licensed in accordance with Chapter 4723. of the Revised Code. The amount of controlled substances 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 engage in the on-site 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 or pharmacist-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 or the director of nursing and another pharmacy or pharmacist-approved supervisory level nurse, may destroy ultimate user controlled substances using an on-site method at the location licensed as a terminal distributor of dangerous drugs. 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 two individuals listed in paragraph (C)(3) of this rule responsible for the destruction.

(5) The record of controlled substance destruction pursuant to paragraph (C)(4) of this rule shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of destruction and made readily retrievable to the board of pharmacy upon request.

6) Controlled substances shall be destroyed pursuant to this paragraph no later than ~~five~~ ten days from the date the patient's controlled substance medication is removed from the medication cart or storage area in accordance with paragraph (C)(1) of this rule.

(D) A state or local correctional facility, as defined in section 5163.45 of the Revised Code, may engage in the on-site destruction of ultimate user (i.e. patient-owned) controlled substances in the custodial care of nursing staff, as follows:

(1) The correctional facility shall be licensed as a category III terminal distributor of dangerous drugs.

(2) The responsible person shall have policies and procedures in place to ensure compliance with and shall comply with all the following:

(a) Upon discontinuation of a patient's controlled substance medication, the responsible person, director of nursing or a licensed pharmacist and another responsible person-approved nurse or corrections officer, 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.

(b) 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.

(c) The responsible person, director of nursing or a licensed pharmacist and another responsible person-approved nurse or corrections officer, may destroy ultimate user controlled substances using an on-site method at the location licensed as a terminal distributor of dangerous drugs. Both individuals shall personally witness and document the destruction of the controlled substance medication pursuant to paragraph (D)(2)(d) of this rule. The on-site method does not have to meet the definition of nonretrievable but must render the drug unavailable and unusable.

(d) 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 two individuals listed in the paragraph (D)(2)(c) of this rule responsible for the destruction. The record of controlled substance destruction shall be maintained on-site at the location licensed as a terminal distributor of dangerous drugs for a minimum of three years from the date of destruction and made readily retrievable to the board of pharmacy upon request.

(e) Controlled substances shall be destroyed no later than ten days from the date the patient's controlled substance medication is removed from the medication cart or storage area in accordance with paragraph (D)(2)(a) this rule.

(E) 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 from the date of destruction and made readily retrievable to the board of pharmacy upon request.