4/27/21

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.

Amend:

- 4729:5-3-02 - 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 drugs immediately by phone and complete a form within thirty days. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222.
- 4729:6-3-02 - 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. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222.

Comments on the proposed rules will be accepted until close of business on May 14, 2021. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Cameron McNamee
Cameron.mcnamee@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Reporting Theft of Loss of Dangerous Drugs

Rule Number(s): 4729:5-3-02, 4729:6-3-02

Date of Submission for CSI Review: 4/27/21

Public Comment Period End Date: 5/14/21

Rule Type/Number of Rules:

New/__rules
Amended/_2___rules (FYR? _Y_)
No Change/___ rules (FYR? __)
Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness,

predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   - 4729:5-3-02, 4729:6-3-02 - Violation of this rule may result in administrative licensure discipline for a pharmacist. Discipline might include reprimand, continuing education, suspension of a license, monetary fine and/or revocation of a license.

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   - 4729:5-3-02, 4729:6-3-02 - A licensee must report theft or significant loss of a dangerous drug immediately by phone and complete a form within thirty days.

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

Amend:

- 4729:5-3-02 - 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 drugs immediately by phone and complete a form within thirty days. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222.
- 4729:6-3-02 - 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. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rule is authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. **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?**
   If yes, please briefly explain the source and substance of the federal requirement.

The rules require adherence to federal laws regarding theft/loss of controlled substance medications.

5. **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 reporting of theft or significant loss of both controlled and non-controlled substances by Ohio licensees.

6. **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.

7. 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.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.
If applicable, please include the date and medium by which the stakeholders were initially contacted.

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

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

The Board did not receive comments on this rule package during the initial public comment process.

11. 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.

12. 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 providing ensuring uniform standards

for the reporting of theft or significant loss of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. 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 a performance-based regulations.

14. 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.

15. 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, incorporated into the Board's internal/external inspection guides, and 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, webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

16. 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; and

The rule package impacts the following:

- 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 all adverse impact (e.g., fees, fines, employer time for compliance,); and

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

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Amend:

- 4729:5-3-02 - 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 drugs immediately by phone and complete a form within thirty days. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222. 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 but it may take additional time to gather the information necessary to complete the form.
- 4729:6-3-02 - 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. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222. 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 but it may take additional time to gather the information necessary to complete the form.

17. 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 reporting standards for the theft or significant loss of prescription drugs from inventory.

Regulatory Flexibility

18. 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.

19. 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 distribution 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.

20. 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. The Board has also developed inspection guides for all license types to help promote self-inspections and voluntary compliance with its rules and laws.

4729:5-3-02 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~~ 9/9/2014);

(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~~ 1305.16 (~~1/21/2016~~ 9/9/2014) of the theft or loss of

any ~~official written order form(s) as defined in division (Q) or section 3719.01 of the Revised Code~~ DEA Form 222.

4729:6-3-02 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~~ 9/9/2014);
(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~~ 1305.16 (~~1/21/2016~~ 9/9/2014) of the theft or loss of any ~~official written order form(s) as defined in division (Q) or section 3719.01 of the Revised Code~~ DEA Form 222.