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:

- 4729:5-5-24 - Provides the requirements for the drug inventory records at an outpatient pharmacy. The rule is updated to clarify that all outpatient pharmacy records must be readily retrievable (e.g., provided within 3-business days upon request).

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

Outpatient Pharmacy Recordkeeping

Rule Number(s): 4729:5-5-24

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/_1___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Rescinded/____ rules (FYR?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.**

   - 4729:5-5-24 - Requires approval by the Board to store records off-site.

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

   - 4729:5-5-24 - 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.**

   - 4729:5-5-24 - Requires written request to store drug records off-site.

   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:

- 4729:5-5-24 - Provides the requirements for the drug inventory records at an outpatient pharmacy. The rule is updated to clarify that all outpatient pharmacy records must be readily retrievable (e.g., provided within 3-business days upon request). Please be advised that "readily retrievable" is a universal standard for all Board of Pharmacy licensees.

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 rule does not implement a federal requirement.

5. **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 licensure and regulation of pharmacies is reserved for state authorities and is required pursuant to Chapter 4729. of the Revised Code.

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 storage of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy 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.

7. **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 a rule written in plain language, licensee compliance with the rule, and minimal questions from licensees regarding the provisions of the rule.

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 rule package was 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 receive one comment on this rule package during the initial public comment process. The comment was not included because it was addressing an issue in the Ohio Medical Marijuana Control Program.

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 regulation is essential to protecting the public's safety by ensuring uniform recordkeeping standards for dangerous drugs at a pharmacy, 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 regulation.

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 rule to ensure that it did 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 rule will be posted on the Board of Pharmacy's web site, incorporated into the Board's outpatient pharmacy inspection guide (www.pharmacy.ohio.gov/OPinspect), and information concerning the rule 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:

- Outpatient pharmacies located in Oio

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:

- 4729:5-5-24 - 4729:5-5-24 - Provides the requirements for the drug inventory records at an outpatient pharmacy. The rule is updated to clarify that all outpatient pharmacy records must be readily retrievable (e.g., provided within 3-business days upon request). A licensee may experience increased administrative costs to capture all the records that must be maintained by the pharmacy as well as to request off-site storage of any outpatient pharmacy records.

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 regulation protects and promotes public safety by ensuring uniform standards for records maintained by an outpatient pharmacy.

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. An example can be accessed here: www.pharmacy.ohio.gov/OPinspect

4729:5-5-24 Drug inventory records and other record keeping provisions.

(A) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.

(B) Temperature logs maintained in accordance with paragraph (B) of rule 4729:5-5-23 of the Administrative Code shall include either:

(1) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(2) For automated systems that provide temperature monitoring, either of the following:

(a) A report that provides, at a minimum, the date and time of observation and the temperature recorded; or

(b) A report that provides temperature excursions, if any, and the date, time, temperature recorded, and length of the noted excursion.

(C) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the positive identification of the licensed or registered health care professional that performed the disposal.

(D) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal, one of whom shall be a pharmacist.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal.

(E) Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

(F) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.

(G) All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years.

(H)

(1) Except as provided for in paragraph (H)(2) of this rule, all records maintained in accordance with this chapter shall be maintained on-site.

(2) An outpatient pharmacy located in this state intending to maintain records at a location other than the location licensed by the state board of pharmacy shall send a request in a manner determined by the board. The board will provide written or electronic notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(I) All records required in accordance with this chapter shall comply with the following:

(1) Be maintained under appropriate supervision and control to restrict unauthorized access, including security features to prevent unauthorized access to computerized records; and

(2) All computerized records shall contain daily back-up functionality to protect against record loss.

(J) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.