1/17/20

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:

- 4729:5-3-08 - Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs, including inspection procedures. The rule is amended to specify the recordkeeping requirements and regulatory requirements and clarify inspection requirements.

Comments on the proposed rules will be accepted until close of business on February 10, 2020. 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):

Non-Resident Terminal Distributor of Dangerous Drugs Amended

Rule Number(s): 4729:5-3-08

Date of Submission for CSI Review: 1/17/20

Public Comment Period End Date: 2/10/20

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__1_ rules (FYR? _Y_)

Rescinded/____ rules (FYR?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.**

Violation of the rule may result in administrative licensure discipline for a location licensed as or applying to be a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation/denial of a license.

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

Requires submission of information upon request as a condition of compliance.

   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:

- 4729:5-3-08 - Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs, including inspection procedures and labeling requirements. The rule is amended to provide greater clarity to out-of-state licensees regarding the requirements of selling dangerous drugs into Ohio.

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 rules are authorized by sections 4729.26, 4729.54, 4729.55 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.

These rules do 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 package exceeds federal requirements because the regulation of dangerous drugs and the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy.

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. The rules proposed under this statutory authority are necessary to promote the public's safety.

Without these regulations, the Board of Pharmacy would not be able to ensure that out-of-state pharmacies delivering drugs to Ohio would comply with certain Ohio regulations intended to protect public safety. It is the Board's responsibility to ensure that the dispensing of dangerous drugs is consistent throughout the state, including out-of-state license holders who dispense dangerous drugs into Ohio.

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/registrant compliance with the rule, and minimal questions from licensees/registrants 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.

The rule in this package was distributed to all Ohio licensed drug distributors and posted to the Board's website as part of a public comment period.

Prior to filing with CSI, the rule was also 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?

CVS Health requested the following changes that were incorporated into the rule draft:

- Removed expiration date from paragraph (B) to not conflict with federal law.
- Added language in paragraphs (E) and (F) that defer to home state and federal laws and regulations should a conflict arise with Ohio laws and rules.
- Clarified paragraph (I) to ensure that non-resident prescribers can issue prescriptions to be dispensed into Ohio.

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 ensuring uniform standards for the licensure and oversight of out-of-state drug distribution, 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 rule to ensure that the regulation does 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, 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 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:

- Nonresident terminal distributors 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:

- 4729:5-3-08 - Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs, including inspection procedures. The rule is amended to specify the recordkeeping and other regulatory requirements and clarify inspection requirements. There may be administrative costs associated with compliance. However, the rule includes standardized labeling and recordkeeping requirements that most pharmacies can currently meet. The amended rule outlines and specifies the

requirements for non-resident terminal distributors of dangerous drugs but does not implement new regulatory requirements. Additionally, the rule incorporates certain exceptions in case of a conflict between Ohio law/rules and the terminal distributor's home state or any federal requirements.

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

The Board 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 for pharmacies dispensing medications into the state.

Regulatory Flexibility

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

The rule incorporates certain exceptions in case of a conflict between Ohio law/rules and the terminal distributor's home state or any federal requirements.

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 practice of pharmacy or 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 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.

4729:5-8-03 Compliance.

A nonresident terminal distributor of dangerous drugs shall:

(A) Maintain~~, in readily retrievable manner,~~ the following records of all dangerous drugs dispensed or personally furnished to persons in this state:

(1) Name, strength, dosage form, the serial number of the prescription, and quantity of the dangerous drug dispensed or personally furnished;

(2) Full name and date of birth of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals; and

(3) Residential address, including the physical street address and telephone number of the patient or owner.

(B) Maintain the following records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code for drugs sold or transferred into this state: name, strength, dosage form, national drug code, ~~expiration date~~ 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.

(C) Maintain all records required by this chapter for a period of three years in a readily retrievable manner.

(D) Label all drugs dispensed or personally furnished into this state with the following minimum information:

(1) The name or "doing business as" (DBA) name and address of the terminal distributor as it appears on the terminal distributor of dangerous drugs license;

(2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals;

(3) The full name of the prescriber or the first initial of the prescriber's first name and the full last name of the prescriber;

(4) Directions for use of the drug;

(5) The date of dispensing;

(6) Any cautions which may be required by federal or state law;

(7) The serial number of the prescription;

(8) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed; and

(9) The quantity of drug dispensed.

(~~B~~E) Comply with all the statutory ~~and regulatory~~ requirements of the state of Ohio set forth in Chapters 4729., 3719., 3715., ~~4752.,~~ and 2925. ~~for controlled substances~~of the Revised Code for all drugs sold, dispensed or personally furnished into this state, ~~including those that are different from federal law,~~ unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state ~~-~~in which it is located or federal statutory or regulatory requirements.

(~~C~~F) Comply with ~~all statutory and~~ the following regulatory requirements of the state of Ohio, ~~for the compounding of dangerous drugs, including those that are different from federal law,~~ unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements~~.~~:

(1) The requirements set forth in this chapter;

(2) The requirements in chapters 4729:5-1 and 4729:5-2 of the Administrative Code;

(3) Theft or significant loss reporting requirements in rule 4729:5-3-02 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(4) Inspection and corrective action requirements in rule 4729:5-3-03 of the Administrative Code;

(5) Licensure verification requirements in rule 4729:5-3-04 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(6) Patient confidentiality requirements in rule 4729:5-3-05 of the Administrative Code;

(7) Internet sales requirements in rule 4729:5-3-08 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state; and

(8) Occasional sale and drug transfer requirements in rule 4729:5-3-09 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state.

(G) Submit to the applicable disciplinary actions set forth in section 4729.57 of the Revised Code and rule 4729:5-4-01 of the Administrative Code.

(H) Operate in compliance with all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(I) Only dispense prescriptions into this state issued by either:

(1) An Ohio prescriber who is authorized pursuant rule 4729:5-1-02 of the Administrative Code; or

(2) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for dangerous drugs in the course of the prescriber's professional practice in a state other than Ohio. ~~laws of the~~

(~~D~~J) Supply, within three business days of a request, all information needed by the board of pharmacy to carry out its responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio.

(~~E~~K) Supply, within three business days of a request, all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio.

(L~~F~~) If the nonresident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription dispensed. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population. The pharmacy shall have sufficient telephone service to provide access to incoming callers.

(~~G~~M) Nonresident terminal distributors shall permit properly identified and authorized state board of pharmacy agents and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles. ~~Facilities and records of nonresident terminal distributors of dangerous drugs shall be subject to inspection by board of pharmacy agents and Ohio drug law enforcement agencies.~~A nonresident terminal distributor of dangerous drugs shall be responsible for all costs incurred by board of pharmacy agents in conducting an inspection. Upon completion of the inspection, the nonresident terminal distributor of dangerous drugs shall have ninety days to reimburse all inspection costs incurred after being notified, electronically or in writing, by the board.

In lieu of an inspection by the board, a nonresident terminal distributor of dangerous drugs may submit any of the following:

(~~1~~1) Inspection reports by a state licensing agency demonstrating compliance with the requirements of this rule ~~may be accepted in lieu of inspection by the board~~.

(2) Inspection reports demonstrating compliance with the requirements of this rule by one of the following ~~may be accepted in lieu of inspection by the board~~organizations:

(a) The national association of boards of pharmacy's verified pharmacy program (VIPP);

(b) An organization approved by the board.

(~~H~~O) Comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and division 4729:8 of the Administrative Code.~~all rules adopted thereunder.~~