5/7/2018

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.

New

- 4729:5-8-01- Definition section for nonresident terminal distributors of dangerous drug rule chapter.
- 4729:5-8-02- Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio.
- 4729:5-8-03- Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs, including inspection procedures.

Rescind

- 4729-10-01- Definition section for nonresident terminal distributors of dangerous drug rule chapter.
- 4729-10-02- Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio..
- 4729-10-03- Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs
- 4729-10-04- Subjects a nonresident terminal distributor of dangerous drugs to inspections by the Board. Includes a provision that inspections conducted by an in-state authority may be used in lieu of an inspection by the Board.

Comments on the proposed rules will be accepted until close of business on **May 25, 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: **Nonresident Terminal Distributors of Dangerous Drugs**

Rule Number(s):

New

- 4729:5-15-01
- 4729:5-15-02
- 4729:5-15-03

Rescind

- 4729-10-01
- 4729-10-02
- 4729-10-03
- 4729-10-04

Date: **5/7/2018**

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.**

New

- 4729:5-8-01- Definition section for nonresident terminal distributors of dangerous drug rule chapter.
- 4729:5-8-02- Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio.
- 4729:5-8-03- Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs, including inspection procedures.

Rescind

- 4729-10-01- Definition section for nonresident terminal distributors of dangerous drug rule chapter.
- 4729-10-02- Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio..
- 4729-10-03- Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs
- 4729-10-04- Subjects a nonresident terminal distributor of dangerous drugs to inspections by the Board. Includes a provision that inspections conducted by an in-state authority may be used in lieu of an inspection by the Board.

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

The proposed rules are authorized by sections 4729.26, 4729.54, 4729.55 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?**

These rules do 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 dangerous drugs and the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy.

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. 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 Ohio regulations. It is the Board's responsibility to ensure that the practice of pharmacy and the dispensing of dangerous drugs are consistent throughout the state, including out-of-state license holders who dispense in Ohio.

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 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.**

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.

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

Rule 4729:5-8-03 was amended due to feedback received from CVS Health to requesting a provision that does not penalize a non-resident pharmacy if complying with Ohio laws would cause the non-resident pharmacy to violate the statutory or regulatory requirements of the state in

which it is located. Additionally, "satisfactory" was removed from paragraph (G) in 4729:5-8-03 as it relates to inspection reports from other states based on feedback provided by CVS Health.

Rule 4729:5-8-03 was further amended to permit the acceptance of inspection reports conducted by non-state entities in lieu of an on-site inspection conducted by Board agents.

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 the rules.

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 rules 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:

- Nonresident terminal 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 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.

New

- 4729:5-8-01- Definition section for nonresident terminal distributors of dangerous drug rule chapter. This rule is definitional and should not have any adverse impact.
- 4729:5-8-02- Requires each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete.
- 4729:5-8-03- Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs, including inspection procedures. There may be additional administrative costs associated with this rule, including compliance with Ohio regulations for compounding dangerous drugs and dispensing controlled substance medications. This depends on the state in which the NRP is located.

15. 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

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

This rule package 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 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.

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.

4729:5-8 – Nonresident Terminal Distributors of Dangerous Drugs

4729:5-8-01 – Definitions.

As used in Chapter 4729:5-8 of the Administrative Code:

(A) "Nonresident terminal distributor of dangerous drugs" means any person, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio. The nonresident terminal distributor of dangerous drugs shall comply with all requirements set forth in this chapter.

(1) A nonresident terminal distributor shall not include a person shipping drugs into this state for destruction or disposal by a reverse distributor.

(B) "Dangerous drug" has the same meaning as defined in section 4729.01 of the Revised Code.

(C) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs in the state where the individual is practicing.

(D) "Pharmacist," as used in division (B) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice pharmacy in the state where he/she is practicing.

(E) “Pharmacy” has the same meaning as defined in section 4729.01.

(F) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that they can be separated out from all other records and, upon request, produced for review no later than three business days to an agent, officer or inspector of the board.

(G) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

4729:5-8-02 Licensure.

(A) Nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio shall obtain a terminal distributor of dangerous drugs license pursuant to sections 4729.54 and 4729.55 of the Revised Code.

(B) A person seeking a license as a nonresident terminal distributor of dangerous drugs shall submit an application to the state board of pharmacy that includes all of the following:

(1) Information necessary to demonstrate the qualifications for licensure set forth in section 4729.55 of the Revised Code.

(2) Certification from the appropriate state licensing agency that the applicant maintains at all times a valid, unexpired license, permit, or registration authorizing the possession and sale of dangerous drugs in the state in which the facility is located and from where dangerous drugs are being sold at retail to residents in Ohio. The certification(s) shall include licenses, permits, or registrations required to cover the categories of dangerous drugs which the nonresident terminal distributor of dangerous drugs will be selling at retail to persons in the state of Ohio.

(3) A copy of the most recent inspection report, any warning notices, notice of deficiency reports, or any other related reports issued by a state licensing agency and drug law enforcement agencies of the state in which it is located or any federal agencies regulating and enforcing laws governing the legal distribution of drugs.

(4) Any other information as determined by the board.

(C) A nonresident terminal distributor shall have a responsible person in accordance with rule 4729:5-2-01 of the Administrative Code.

4729:5-8-03 Compliance.

A nonresident terminal distributor of dangerous drugs shall:

(A) Maintain, in readily retrievable manner, records of all dangerous drugs sold at retail to persons in Ohio for a minimum of three years.

(B) Comply with all the statutory and regulatory requirements of the state of Ohio for controlled substances, including those that are different from federal law, unless such compliance would cause the nonresident terminal distributor of dangerous drugs to violate the statutory or regulatory requirements of the state in which it is located.

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

(D) 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) 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.

(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) 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.

(1) Inspection reports by a state licensing agency may be accepted in lieu of inspection by the board.

(2) Inspection reports by one of the following organization may be accepted in lieu of inspection by the board:

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

(b) An organization approved by the board.

(H) Comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and all rules adopted thereunder.