CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Nonresident Terminal Distributors of Dangerous Drugs

Rule Number(s): No Change: 4729-10-02; 4729-10-03; 4729-10-04

Amended: 4729-10-01

Date: 1/16/2014

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✓ Amended	Rescinded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.

This rule package requires the following:

No Change Rules

- **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. A nonresident terminal distributor of dangerous drugs includes any entity

located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio.

- **4729-10-03:** Provides the requirements for nonresident terminal distributors to operate in the state of Ohio. These requirements include maintaining records of drug sold, compliance with federal and state laws and, if a pharmacy, the license holder must offer to counsel the patient.
- **4729-10-04:** Makes nonresident terminal distributors subject to inspection by board of pharmacy agents and Ohio drug law enforcement agencies.

Proposed Rule Changes:

- **4729-10-01:** Makes a technical correction to correspond with an updated section of the Ohio Revised Code.

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

The proposed rules are authorized by section 4729.26 of the Ohio Revised Code. Additional authorizing sections of the Revised Code include: 4729.01, 4729.54, 4729.55, 4729.551 and 4729.57.

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 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 the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice, including admission to practice, standards of practice, and discipline of pharmacists. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy traditionally has been left to the state board 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 Codes authorizes the Ohio State Board of Pharmacy to adopt rules governing the practice of pharmacy, including the prescribing and dispensing of dangerous drugs. The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of the Ohio Revised Code to promote the public's safety.

Without these regulations, the Board of Pharmacy would not be able 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 these rules.

Development of the Regulation

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

The rules were reviewed and approved by the Ohio State Board of Pharmacy's Rules Review Committee. The committee comprised a broad array of stakeholders including:

- Gahm's Pharmacy
- Walgreens
- Nationwide Children's Hospital
- Hock's Vandalia Pharmacy
- Kroger Corporate
- Toledo Hospital
- Ritzman Pharmacy
- Doctors Hospital – OhioHealth
- Akron General Medical Center
- Northeast Ohio Medical University

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

For the no change rules (4729-10-02; 4729-10-03; 4729-10-04), the Ohio State Board of Pharmacy Rules Review Committee reviewed the current regulations as part of the mandated 5-year rule review process. No additional changes to the rule were recommended.

For the proposed rule change (4729-10-01), the Ohio State Board of Pharmacy Rules Review Committee reviewed and approved the proposed change identified by Board staff.

Following the approval of the rule by the Rules Review Committee, the Ohio State Board of Pharmacy formally approved the rule package.

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. However, input was solicited from registered pharmacists through the Board's Rules Review Committee representing health systems, hospitals and retail establishments.

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?**

Since the regulation of out-of-state providers of dangerous drugs is essential to the protecting the public's safety, the Ohio State 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 r*equired 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 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. It was the determination of the Board's Rule Review Committee that the rule package did not lend itself to a performance-based regulation.

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 Legal Affairs reviewed the Ohio Administrative Code to ensure that these regulations do not duplicate existing Ohio rules.

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 Pharmacy Board'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. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board staff receive regular updates on rules via a quarterly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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;

This rule package impacts nonresident terminal distributor of dangerous drugs. This includes any entity located outside of Ohio that ships, mails or delivers in any manner, dangerous drugs at retail into Ohio. Many of these businesses are categorized as mail-order pharmacies.

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

License fees are required for all nonresident terminal distributors of dangerous drugs. In addition, a new out-of-state TDDD application includes a criminal records check. The total estimated time to submit this application is approximately two hours.

Violation of the rules may also result in administrative licensure discipline for the the location licensed as a terminal distributor of dangerous drugs (TDDD). Discipline might include reprimand, fines, suspension of the license, and/or revocation of the license.

c. Quantify the expected adverse impact from the regulation.

An entity that wishes to be licensed as a nonresident terminal distributor of dangerous drugs is required to pay an annual licensure fee that ranges from $112.50 to $150.00, depending on type of drugs possessed by the license holder.

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

The Ohio State Board of Pharmacy is committed to ensuring that dangerous drugs are distributed safely and in accordance with Ohio law.

Licensure of nonresident terminal distributors is essential to preventing the diversion of dangerous drugs. The purpose of a TDDD license is to ensure that drugs are stored, dispensed and destroyed in accordance with Ohio law. The TDDD license permits the Ohio State Board of Pharmacy to conduct unannounced inspections of sites where drugs, including controlled substances, are stored and dispensed to safeguard against tampering or diversion. A license application gathers information that enables the Board of Pharmacy to conduct criminal and administrative background checks on the distributor's responsible person. These checks uncover prior professional disciplinary action and/or pending charges or convictions for felonies or non-traffic misdemeanors. Without such background checks, individuals with drug convictions or who have been sanctioned by their licensing boards have unfettered access to dangerous drugs.

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, applies to all nonresident licensed locations that dispense dangerous drugs.

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 Ohio State 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 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 members are available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek an update on current regulations. Additionally, field staff (i.e. compliance officers) are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.