CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Dangerous Drugs

Rule Number(s): No Change: 4729-9-08; 4729-9-23

Amended: 4729-9-02

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✓ Amended	Rescinded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

- **4729-9-08:** States that any change in ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license.

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- **4729-9-23:** Permits the packaging of multiple drugs in the same container under certain conditions.

Proposed Rule Changes:

- **4729-9-02:** Removes the requirement that all pharmacies possess a paper copy of the references necessary to conduct the practice of pharmacy. The regulation would require the pharmacy to either have a paper copy or ensure access to the appropriate references via electronic means.

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.

Rules 4729-9-08 & 4729-9-02 are authorized under 4729.51, 4729.52, 4729.54, and 4729.55 of the Ohio Revised Code. These sections primarily deal terminal and wholesaler distributors of dangerous drugs and the selling, purchasing, distributing, or delivering dangerous drugs.

Rule 4729-9-23 is authorized under 3715.521, 3715.63, and 3715.64 of the Ohio Revised Code. These sections primarily address misbranded, adulterated and expired drugs.

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 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 Codes authorizes the 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.

If these regulations were not in existence the Board would not be able to perform the proper checks on licensees that change ownership, business or trade name, category, or address. Proper documentation and background checks are essential to protecting the public from any entity that has access to dangerous drugs. Additionally, this regulation ensures that all pharmacists have access to rules and references necessary to conduct the practice of pharmacy.

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 and prescribers of dangerous drugs 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.**

The rules were reviewed and approved by the Ohio State Board of Pharmacy's Rules Review Committee. The committee is comprised of 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 amended rule (4729-9-02), the Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed change. Any feedback from the committee was incorporated into the rule package.

For the no change rules (4729-9-08; 4729-9-23), 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.

Following the approval of the rules 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 practice.

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 regulations are 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 required outcome, but don't dictate the process* the regulated stakeholders must use to achieve compliance.**

Rule 4729-9-02 is considered a performance-based regulation in that is does not dictate the process used by the pharmacy to achieve compliance. The two no-change rules (4729-9-08 & 4729-9-23) are specific in nature because they are intended to protect the health and safety of the public.

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 regulations.

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 information 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;

The rules impact pharmacies, pharmacists, facilities licensed as terminal distributors of dangerous drugs and pharmaceutical wholesalers.

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

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

In addition, businesses that change ownership, name, address or license category as they are required to apply for new terminal distributor or wholesale distributor of dangerous drugs license. A new application requires a criminal records check. The total estimated time to submit a new application is approximately two hours.

c. Quantify the expected adverse impact from the regulation.

4729-9-08: Requires any change in ownership, business or trade name, category, or address of a terminal or wholesale distributor of dangerous drugs requires a new application, required fee, and license.

Will result in a cost to businesses that change ownership, name, address or license category as they are required to apply for a new terminal distributor or wholesale distributor of dangerous drugs license. A terminal distributor of dangerous drugs license, depending the drugs stored at the location, costs between $45.00 and $150.00 per year. A wholesale distributor of dangerous drugs license costs between $750.00 and $787.00 per year.

4729-9-23: Permits the packaging of multiple drugs in the same container under certain conditions.

Will require minimal staff time to ensure compliance, as it is an established practice in effect since 2003.

4729-9-02: Removes the requirement that all pharmacies possess a paper copy of the references necessary to conduct a pharmacy. The regulation would require the pharmacy to either have a paper copy or ensure access to the appropriate references via electronic means.

May result in a small cost savings, as pharmacies are not required to purchase updated reference materials if they have access to the required information online.

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

A change in ownership, business or trade name, category, or address of a terminal distributor requires a new license to protect the safety of the public. A Terminal Distributor of Dangerous Drugs (TDDD) License is required for any location engaged in the sale of dangerous drugs at retail or any person, other than a wholesale distributor or a pharmacist, who has possession,

custody, or control of dangerous drugs, including controlled substances, for any purpose other than for that person's own use and consumption. 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.

A new application for a change ownership, name, address or license category for a wholesale distributor is important so that the Board can be certain that granting the license is in the public's interest. A Wholesale Distributor of Dangerous Drugs (WDDD) is an individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions who is engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

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 pharmacists and 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.