7/27/15

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 Ohio State 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.

Amended Rules

- **4729-16-08:** Provides the requirements for nonresident pharmacies that ship compounded drugs into Ohio. Clarifies that nonresident pharmacies can utilize an inspection report from any state to meet the requirements of the rule. In addition, it specifies that the required inspection reports must show compliance with USP 797 and 795 rather than all of the requirements listed in OAC 4729-16-03.
- **4729-16-02:** Provides the requirements for outsourcing facilities that provide non-patient specific compounded drugs. Clarifies that both human and animal outsourcing facilities are permitted and that outsourcing facilities shall comply with all of the applicable requirements for a wholesale distributor of dangerous drugs and current good manufacturing practices.

Comments on the proposed rules will be accepted until close of business on August 11, 2015. Please send all comments to the following email address:
Cameron.mcnamee@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: Ohio State Board of Pharmacy

Regulation/Package Title: Compounding

Rule Number(s): Amended: 4729-16-08; 4729-16-02;

Date: 07/27/2015

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Amended	**Rescinded**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.

Amended Rules

- **4729-16-08:** Provides the requirements for nonresident pharmacies that ship compounded drugs into Ohio. Clarifies that nonresident pharmacies can utilize an inspection report from any state to meet the requirements of the rule. In addition, it specifies that the required inspection reports must show compliance with USP 797 and 795 rather than all of the requirements listed in OAC 4729-16-03.
- **4729-16-02:** Provides the requirements for outsourcing facilities that provide non-patient specific compounded drugs. Clarifies that both human and animal outsourcing facilities

are permitted and that outsourcing facilities shall comply with all of the applicable requirements of a wholesale distributor of dangerous drugs and current good manufacturing practices.

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

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.01, 4729.51, 4729.52, 4729.54, 4729.55 and 4729.56.

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?

4729-16-02 is a requirement of federal law. It is required for any outsourcing facility to operate in Ohio and ship non-patient specific compounded drugs into the state.

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 State of Ohio Board of Pharmacy including the distribution of compounded drug products. The State of Ohio Board of Pharmacy regulates all aspects of pharmacy practice. 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.

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 state board of pharmacy to adopt rules governing the practice of pharmacy, which includes the regulation of entities that store and ship dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules 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.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the previously mentioned sections of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide uniform requirements for outsourcing facilities that operate in Ohio and ship drugs into the state.
- Provide uniform requirements for nonresident pharmacies that ship compounded drugs into 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 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 State of Ohio Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- Select Specialty Hospital – Akron
- Berger Health System
- The Kroger Company
- Meijer
- Nationwide Children's Hospital
- Fort Hamilton Hospital
- Central Ohio Compounding Pharmacy
- Healthspan Physicians and Integrated Care
- Cedarville University School of Pharmacy
- Fairview Hospital – Cleveland Clinic
- OhioHealth
- Wal-Mart
- Pharmacy Systems, Inc.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into 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 the rule.

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 rules for the preparation of compounded 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-bas*ed regulations define the required outcome, but don't dictate the process* the regulated stakeholders must use to achieve compliance.**

The Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Legal Affairs and Pharmacist Compliance Supervisor reviewed the proposed rules 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 Pharmacy Board's web site, information concerning the rule 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 monthly 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 rule package impacts the following:

- Non-resident pharmacies that compound and ship drugs to Ohio;
- Outsourcing facilities.

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 pharmacist, pharmacy intern or 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.

4729-16-08: Provides the requirements for nonresident pharmacies that ship compounded drugs into Ohio. Clarifies that nonresident pharmacies can utilize an inspection report from any state to meet the requirements of the rule. In addition, it specifies that the required inspection reports must show compliance with USP 797 and 795 rather than all of the requirements listed in OAC 4729-16-03. As this seeks to clarify an existing rule, this should not result in additional compliance costs as the original rule requires. The rule itself does have the following costs associated with its implementation:

- Requires nonresident pharmacies to be licensed as terminal distributors of dangerous drugs. Depending on whether the location will be dispensing controlled or non-controlled drugs, the annual license cost ranges from $112.50 to $150.00. It also takes approximately 30 minutes to complete the license application. In addition, the pharmacy must demonstrate compliance with Ohio law by submitting a recent state inspection report, an inspection report conducted by another state or an inspection report provided by the National Association of Boards of Pharmacy's Verified Pharmacy Program (VPP). State inspection reports are available at no-cost. The VPP inspection costs anywhere from $2,500 to $3,000.

4729-16-02: Provides the requirements for outsourcing facilities that provide non-patient specific compounded drugs. Clarifies that both human and animal outsourcing facilities are permitted and that outsourcing facilities shall comply with all of the applicable requirements for a wholesale distributor of dangerous drugs and current good manufacturing practices. As this seeks to clarify an existing rule, this should not result in additional compliance costs as the original rule requires. This rule itself has the following licensing requirements:

- Outsourcing Facility License from the United State Food and Drug Administration. This annual establishment fee is approximately $15,000. However, the FDA does grant a discount to small businesses that would only have to pay an annual fee of $5,000. (It should be noted that licensure as an outsourcing facility through the FDA is a federal requirement for any facility that would like to ship non-patient specific sterile compounded drugs).[1]
- Ohio License as a Wholesale Distributor of Dangerous Drugs. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual license cost ranges from $750 to $787.50. It also takes approximately one hour to complete the license application.
- If an outsourcing facility also would like to provide patient-specific prescriptions, it would also have to get an Ohio license as a Terminal Distributor of Dangerous Drugs. Depending on whether the location will be dispensing controlled or non-controlled drugs, the annual license cost ranges from $112.50 to $150.00. It also takes approximately 30 minutes to complete the license application.

[1] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf

Regulatory Flexibility

15. 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.

16. 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 is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

17. 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, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-16-08 Drugs compounded by a nonresident pharmacy.

(A) A nonresident pharmacy as defined in rule 4729-16-01 of the Administrative Code is prohibited from shipping compounded drugs into Ohio unless it is pursuant to a patient specific prescription.

(B) A nonresident pharmacy as defined in rule 4729-16-01 of the Administrative Code shall meet all of the following in order to ship, mail, or deliver, in any manner, compounded drugs into Ohio:

(1) Obtain licensure as a nonresident terminal distributor of dangerous drugs pursuant to Chapter 4729-10 of the Administrative Code.

(2) If the nonresident pharmacy is applying for an initial nonresident terminal distributor of dangerous drugs license, renewal, or their license has lapsed, they must provide one of the following, in a manner prescribed by the board, with their application:

(a) The most recent inspection report that is less than two years old that demonstrates compliance with paragraphs (H) and (I) of this rule ~~4729-16-03 of the Administrative Code~~ conducted by an agent of the regulatory or licensing agency in the pharmacy's resident jurisdiction or an agent of a regulatory or licensing agency from another licensing jurisdiction; or

(b) The most recent inspection report that is less than two years old that demonstrates compliance with paragraphs (H) and (I) of this rule ~~provided~~ conducted by the national association of boards of pharmacy's verified pharmacy program as defined in rule 4729-16-01 of the Administrative Code.

(C) Notwithstanding submission of an inspection report from a source acceptable to the board, the board may deny an application or suspend a license on the grounds that the nonresident pharmacy failed to comply with applicable laws or regulations. The nonresident pharmacy would have the opportunity for a hearing before the board.

(D) The board may grant a one-year, one-time extension to nonresident pharmacies in the event an inspection report is not available at the time of application or renewal and documentation is presented verifying intent to comply with this rule.

(E) A nonresident pharmacy is required to report to the state board of pharmacy immediately upon discovery, by telephone and follow-up in writing within thirty days, any of the following:

(1) A violation of section 4729.16 of the Revised Code or any other violation of the Ohio Revised Code or Ohio Administrative Code that could potentially cause patient harm;

(2) A citation or violation against the nonresident pharmacy or the owner(s), responsible person, agent, employee or officer of the nonresident pharmacy by any pharmacy regulatory or licensing agency that results in any the following:

(a) Monetary penalty;

(b) Administrative hearing;

(c) Suspension or revocation of a license; or

(d) Violations of laws or regulations that could potentially cause patient harm.

(3) Any criminal conviction(s) of the owner(s), responsible person, agent, employee or officer of the nonresident pharmacy.

(4) Any adverse event related to improper compounding or product defect.

(F) Failure to report the required information in paragraph (E) of this rule may result in a monetary penalty and/or the suspension, revocation, or refusal to grant or renew any license as a terminal distributor of dangerous drugs.

(G) This rule does not apply to a nuclear pharmacy that compounds radiopharmaceuticals pursuant to rule 4729-15-01 of the Administrative Code.

(H) For all non-sterile compounded prescriptions, the pharmacy shall comply with chapter <795> of the United States pharmacopeia, USP 38 – NF 33, or any official supplement thereto (05/01/2015).

(I) For all sterile compounded prescriptions, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 – NF 33, or any official supplement thereto (05/01/2015).

4729-16-02 Sterile compounded drugs provided by an outsourcing facility.

(A) An entity may provide, without a patient specific prescription, a non-patient specific sterile compounded drug preparations ~~preparation for human use only~~, if the following conditions apply:

(1) The entity is registered with the United States food and drug administration as an outsourcing facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015); ~~and~~

(2) The entity is licensed as a wholesale distributor of dangerous drugs pursuant to section 4729.52 of the Revised Code with an outsourcing facility classification. The entity must include a licensed pharmacist as the responsible person on the license~~.~~; and

(B) This rule does not apply to pharmacies that compound drugs for direct administration by a prescriber pursuant to rule ~~4729-9-25~~ 4729-16-07 of the Administrative Code.

(C) The outsourcing facility shall comply with all labeling and recordkeeping requirements pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015).

(D) If an entity licensed as a wholesale distributor of dangerous drugs with an outsourcing facility classification pursuant to paragraph (A) of this rule dispenses patient specific drugs, it must also register as a terminal distributor of dangerous drugs. All laws and rules applicable to the terminal distributor license shall apply to dispensing of patient specific drugs.

(E) The entity is licensed as a wholesale distributor of dangerous drugs with an outsourcing facility classification shall comply with all of the following:

(1) All applicable federal, state, and local laws and regulations, including but not limited, to the following:

(a) Chapter 4729-9 of the Administrative Code;

(b) Section 503B of the Federal Food, Drug, and Cosmetic Act (5/28/2015); and

(c) Current good manufacturing practices pursuant to Section 501 of the Federal Food, Drug and Cosmetic Act (5/28/2015)