OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: **614-466-4143** E-MAIL: **exec@bop.ohio.gov** FAX: **614-752-4836**

TTY/TDD: Use the Ohio Relay Service: 1-800-750-0750 URL: http://www.pharmacy.ohio.gov

7/8/14

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 rule.

New Rules

- **4729-16-01:** Provides definitions for a new rule chapter on compounding of dangerous drugs.
- **4729-16-02:** Provides the requirements for operation of an outsourcing facility. Outsourcing facilities provide sterile non-patient specific compounded drugs.

Comments on the proposed rules will be accepted until close of business on **July 22, 2014**. Please send all comments to the following email address:

Cameron.mcnamee@bop.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): New: 4729-16-01; 4729-16-02;

Date: 7/8/2014

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Amended	Rescinded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.

New Rules

- **4729-16-01:** Provides definitions for a new rule chapter on compounding of dangerous drugs.
- **4729-16-02:** Provides the requirements for operation of an outsourcing facility. Outsourcing facilities provide sterile non-patient specific compounded drugs.

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?

These rules are being adopted to enable a federally registered outsourcing facility to operate in Ohio. In addition, this will enable nonresident entities to ship sterile non-patient specific compounded drugs into the state. This practice is authorized by section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which was recently added by the Drug Quality and Security Act (DQSA) signed into law in November 2013.

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 and oversight of facilities providing dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Board regulates all aspects relating to selling, purchasing, distributing, or delivering dangerous drugs.

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 and oversight of the selling, purchasing, distributing, or delivering 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 Ohio State Board of Pharmacy would not be able to:

- Provide uniform licensing requirements to ensure the safe operation of outsourcing facilities providing sterile non-patient specific compounded drugs.

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 rules.

Development of the Regulation

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

These rules were reviewed and approved by the Ohio State Board of Pharmacy's Compounding Rules Review Committee on July 2, 2014. The committee is comprised of a broad array of stakeholders including:

- OhioHealth
- Trumbull Memorial Hospital
- Pack Pharmacy
- Clinical Apothecary
- Buderer Drugs
- Okuley Pharmacy
- Central Ohio Compounding
- Compounding Pharmacy of Green
- Medicine Shoppe
- Central Admixture Pharmacy Services

The Board also received comments from Pharmedium and Ravenswood Drug.

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 Ohio State Board of Pharmacy Compounding Rules Review Committee and the stakeholders listed above reviewed, provided comments and approved the proposed rules. Following the approval of the package by the Rules Review Committee, the Ohio State Board of Pharmacy formally approved the rules for filing with CSI.

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, outsourcing facilities 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?**

As the regulations are essential to protecting the public's safety by ensuring uniform rules for the oversight of outsourcing facilities, 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.**

The agency 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 for all outsourcing facilities. 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 Compliance reviewed the Ohio Administrative Code to ensure that the rules do not duplicate an existing Ohio 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 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 rules. 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 rule package impacts the following:

- Entities wishing to be licensed as an outsourcing facility in Ohio.

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 a pharmacist or an outsourcing facility licensed as a wholesale distributor of dangerous drugs license. Discipline might include reprimand, fines, suspension of the license, required course work, and/or revocation of the license.

In addition, there will be licensing costs to comply with rule 4729-16-02 (see section c).

c. Quantify the expected adverse impact from the regulation.

4729-16-01: Provides definitions for a new rule chapter on compounded drugs. This is a definitional section and should have no compliance costs.

4729-16-02: Provides the requirements for operation of an outsourcing facility. Outsourcing facilities provide sterile non-patient specific compounded drugs. This regulation 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.

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 uniform standards for the operation outsourcing facilities.

Regulatory Flexibility

16. 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.

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 or 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.

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

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 an update 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.

4729-16-01 DEFINITIONS

(A) As used in this section of the Administrative Code:

(1) ”Outsourcing facility” means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States Food and Drug Administration section 503B of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(2) "Sterile" means a dosage form free of living microorganisms (aseptic).

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 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 (11/27/2013); and

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

(B) This rule does not apply to pharmacies that compound drugs for direct administration by a prescriber pursuant to rule 4729-9-25 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 (11/27/2013).

(D) If an entity licensed as a wholesale distributor of dangerous drugs with an outsourcing facility classification pursuant to division (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 only apply to dispensing of patient specific drugs.