3/16/2017

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.

Rescinded

- 4729-16-07: Establishes requirements for the compounding of drugs for human use at an in-state pharmacy for direct administration by a prescriber, and the requirements for the direct administration by a prescriber.
- 4729-16-10: Establishes requirements for the exemption to allow an in-state pharmacy to compound a non-patient specific drug for use by an in-state health care facility in the event of a drug shortage.

Comments on the proposed rules will be accepted until close of business on April 3, 2017. 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: State of Ohio Board of Pharmacy

Regulation/Package Title: Drug Compounding

Rule Number(s): Rescinded: 4729-16-07; 16-10

Date: 3/16/2017

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Amended	**Rescinded**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.

Rescinded

- 4729-16-07: Establishes requirements for the compounding of drugs for human use at an in-state pharmacy for direct administration by a prescriber, and the requirements for the direct administration by a prescriber.
- 4729-16-10: Establishes requirements for the exemption to allow an in-state pharmacy to compound a non-patient specific drug for use by an in-state health care facility in the event of a drug shortage.

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

The proposed rules are authorized by sections 4729.26 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?**

The proposed rescission of the rules implements a requirement found in section 503A of the Federal Food, Drug, and Cosmetic Act.

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 does not exceed federal requirements.

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 distribution of dangerous drugs.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the State of Ohio Board of Pharmacy would not be able to ensure proper compliance with federal law.

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 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 proposed recessions in this package were the result of initial consultations with the U.S. Food and Drug Administration. An Ohio pharmacy has already been disciplined by the FDA for preparing compounded drug products in accordance with these rules. Therefore, it is necessary to rescind these rules as soon as possible.

Prior to filing with CSI, the rules were also 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?

For the proposed rules, the U.S. Food and Drug Administration provided the following input:

> On December 29, 2016, FDA issued a final guidance, entitled Prescription Requirement under Section 503A of the Federal Food, Drug, and Cosmetic Act. It is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf. This guidance sets forth *FDA's policy concerning certain* prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act). It addresses, among other things, compounding for office use (or office stock).
>
> *The guidance states that "for each drug compounded under section* 503A, the compounder must obtain a valid patient-*specific prescription order," and that "the compounder can* distribute compounded drugs under section 503A only pursuant to such a valid patient-specific prescription (i.e., the compounder receives a valid patient-specific prescription before the compounded drug product leaves the compounding *facility)."* We recognize that some state boards of pharmacy may authorize the writing of prescriptions that do not include individual patient names. Such prescriptions, however, do not meet the requirement of a patient-specific prescription in section 503A.
>
> *We believe that in order to preserve access to drugs compounded for "office use" for* patients who need them while protecting patients from poor quality compounded medications, it is critical we enforce the statutory language in section 503A of the FD&C Act that requires that compounding of medications be based on the receipt of a valid prescription for an identified individual patient, and that we direct healthcare facilities that purchase drugs compounded for office-use to compounders that have registered with FDA as outsourcing facilities.

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.

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 rescission of the regulations are necessary to comply with federal law, 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 regulations 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?

This is a rule recession so it does not duplicate an existing 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 notice of recession of the rules will be posted on the Pharmacy Board's web site, information concerning the recession of 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/recession 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, email updates from the Director of Policy and Communications 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:

- Compounding pharmacies; and
- Prescribers using non-patient specific compounded 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 pharmacist or terminal distributor that continues to provide non-patient specific compounded drugs for in-office use. 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.

Rescinded

- 4729-16-07: Pharmacies may lose revenue from not being able to compound non-patient specific drugs. Prescribers will have to obtain non-patient specific compounded drugs for in-office use from FDA approved outsourcing facilities, which may increase costs. The Board of Pharmacy does provide a list of outsourcing facilities on its website: www.pharmacy.ohio.gov/outsourcing
- 4729-16-10: Pharmacies may lose revenue from not being able to compound non-patient specific drugs. Health systems will have to obtain non-patient specific compounded drugs for in-office use from outsourcing facilities, which may increase costs. The Board of Pharmacy does provide a list of outsourcing facilities on its website: www.pharmacy.ohio.gov/outsourcing

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

The Board determined that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety and compliance with federal law. In particular, they ensure uniform regulations that allow for:

- The safety and security of compounded drugs; and
- Compliance with federal law.

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

RESCIND:

4729-16-07 Drugs compounded for human use at an in-state pharmacy for direct administration by a prescriber.

(A) This rule applies to compounded drugs products for human use.

(B) The following requirements do not apply to:

(1) A nuclear pharmacy that compounds radiopharmaceuticals. A radiopharmaceutical must be prepared pursuant to Chapter 4729-15 of the Administrative Code.

(2) An outsourcing facility as defined in rule 4729-16-01 of the Administrative Code. An outsourcing facility must comply with the requirements of rule 4729-16-02 of the Administrative Code.

(3) A non-resident pharmacy as defined in rule 4729-16-01 of the Administrative Code. A nonresident pharmacy shall comply with the requirements of rule 4729-16-08 of the Administrative Code.

(4) An in-state pharmacy granted an exemption pursuant to rule 4729-16-10 of the Administrative Code.

(C) For all non-sterile compounded drug products, the in-state pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(D) For all sterile compounded drug products, the in-state pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(E) A pharmacist working at an in-state pharmacy as defined in rule 4729-16-01 of the Administrative Code licensed as a terminal distributor of dangerous drugs may compound and provide without a prescription a non-patient specific drug pursuant to a request made by a prescriber, or by an agent of the prescriber, for a drug to be used by the prescriber for the purpose of the direct administration to patients in the course of the prescriber's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:

(1) The drug is compounded and provided to a prescriber as an occasional exception to the normal practice of dispensing drugs pursuant to patient specific prescriptions .

(2) The in-state pharmacy shall only provide those compounded drugs that are not commercially available to a prescriber which are needed:

(a) To treat an emergency situation;

(b) For an unanticipated procedure for which a time delay would negatively affect a patient outcome;

(c) For diagnostic purposes.

(F) The in-state pharmacy shall not supply more than a seventy-two hour supply of a non-patient specific compounded drug to a prescriber at a single location. A prescriber shall not have more than a seventy-two hour supply of a compounded drug at a single location at any given time. The seventy-two hour supply provided to the prescriber shall be determined by previous administration patterns provided by a prescriber to the pharmacist. The limitation of a seventy-two hour supply shall not apply to either of the following:

(1) Compounded non-sterile drug products for topical administration, pursuant to paragraphs (E)(2)(b) and (E)(2)(c) of this rule, shall be supplied to a prescriber in which the quantity does not exceed sixty grams or sixty milliliters at a single location. A prescriber shall not have more than sixty grams or sixty milliliters of a specific compounded drug at a single location at any given time; or

(2) Compounded non-sterile drug products intended to treat an emergency situation, pursuant to paragraph (E)(2)(a) of this rule, may be provided to a prescriber in a quantity required to sufficiently treat individuals in the event of an emergency situation.

(G) The in-state pharmacy shall not sell a compounded drug to another pharmacy or wholesaler.

(H) Prescribers shall only administer a requested non-patient specific compounded drug directly to their own patients. Prescribers shall not:

(1) Dispense or personally furnish a compounded drug to a patient;

(2) Sell a compounded drug to another prescriber;

(3) Sell a compounded drug to a pharmacy; or

(4) Return a compounded drug to the supplying pharmacy.

(I) The labeling of a compounded drug product must contain the following:

(1) The statement "For direct patient administration only" displayed prominently;

(2) The statement "Not for resale" displayed prominently;

(3) Proper storage conditions;

(4) Beyond use dates;

(5) The name(s) of the active and inactive ingredients;

(6) The amount or percentage of active drug ingredients;

(7) The quantity of compounded drug provided;

(8) The route of administration;

(9) The pharmacy name, address, and telephone number;

(10) The pharmacy control number assigned to the compounded drug preparation ;and

(11) The statement "Compounded Drug Product" or other similar statement.

(J) Compounded drug product containers that are too small to bear a complete label pursuant to paragraph (I) of this rule must bear a label that contains at least the following information:

(1) "Not for resale";

(2) The storage conditions if other than room temperature;

(3) The beyond use date;

(4) The drug name(s), including all active ingredients;;

(5) The drug strength(s);

(6) The route of administration;

(7) The pharmacy control number;

(8) The pharmacy name.

(K) In all cases, a complete label meeting the requirements of paragraph (H) of this rule must be applied to the outside container in which such compounded product is supplied.

(L) The sale of a compounded drug product to a prescriber is considered a wholesale sale as defined in section 4729.01 of the Revised Code. A pharmacy is required to follow the record keeping requirements for wholesale sales listed in paragraph (H) of rule 4729-9-16 of the Administrative Code.

(M) A pharmacy shall follow the compounding requirements pursuant to rules 4729-16-03 and 4729-16-06 of the Administrative Code current professional compounding standards, and all applicable federal and state laws, rules, and regulations.

(N) No in-state pharmacy shall sell any amount of non-patient specific prescriber administered compounds for human use in excess of five per cent of the total amount of compounded drug products sold and/or dispensed from their pharmacy. The five per cent limitation shall be calculated on an annual basis and shall reference the number of dosage units. If the five per cent limitation is exceeded, then the pharmacy must apply to become an outsourcing facility pursuant to rule 4729-16-02 of the Administrative Code.

RESCIND:

4729-16-10 In-state pharmacy compounding for drug shortages.

(A) In the event of a drug shortage as defined in rule 4729-16-01 of the Administrative Code, an in-state pharmacy may request an exemption from rule 4729-16-07 of the Administrative Code from the state board of pharmacy.

(B) Upon provision of an exemption, a pharmacist working at an in-state pharmacy, as defined in rule 4729-16-01 of the Administrative Code, licensed as a terminal distributor of dangerous drugs may compound and provide without a prescription a non-patient specific drug pursuant to a request made by a medical director of an in-state health care facility, as defined in rule 4729-16-01 of the Administrative Code, for a drug that is to be used by the facility for the purpose of direct administration to patients.

(C) In order to obtain an exemption, the responsible pharmacist for the in-state pharmacy and the medical director of an in-state health care facility or Ohio licensed pharmacist who is authorized by the in-state health care facility to act on behalf of the medical director must notify the executive director of the state board of pharmacy in a manner prescribed by the board.

(D) The executive director may, on behalf of the board, place restrictions on the exemption including, but not limited to, the following:

(1) A limit on the quantity of the drug(s) compounded without a patient specific prescription by the in-state pharmacy;

(2) A limit on the time the exemption shall be in effect;

(E) The board shall review each exemption notification provided to the executive director and may place restrictions on the exemption including, but not limited to, the following:

(1) A limit on the quantity of the drug(s) compounded without a patient specific prescription by the in-state pharmacy; and

(2) A limit on the time the exemption shall be in effect.