



OHIO STATE BOARD OF PHARMACY

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5/6/14

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.

Proposed Rule Change

- 4729-5-38: Authorizes a licensed pharmacist to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older.

You can view the proposed rule below.

Comments on the proposed rules will be accepted until close of business on May 20, 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: Pharmacists-Administrative Provisions

Rule Number(s): Amended: 4729-5-38

Date: 5/6/2014

Rule Type:

New
✓ Amended

5-Year Review
Rescinded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.

Proposed Rule Change

- **4729-5-38:** Authorizes a licensed pharmacist to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older.

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

The proposed rule is authorized by section 4729.26 and 4729.41 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 rule does 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, administration of vaccinations and the 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.

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. Section 4729.41 of the Ohio Revised Code requires the state board of pharmacy to adopt rules regarding the administration of vaccines by pharmacists to individuals eighteen years of age or older, including the addition of vaccines that can be administered. 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 this regulation, the Ohio State Board of Pharmacy would not be able to authorize pharmacists to provide vaccines in response to current and possible future measles and mumps outbreaks 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 and prescribers of dangerous drugs regarding the provisions of the rules. If possible, the Board will also monitor vaccination rates among the target population.

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:

- OhioHealth
- Trumbull Memorial Hospital
- Kroger
- Hock's Pharmacy
- Northeast Ohio Medical University
- Nationwide Children's Hospital
- Giant Eagle
- Absolute Pharmacy
- St Ann's Hospital
- Akron General
- Cedarville 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 proposed rule change, the Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. Following the approval of the package by the Rules Review Committee, the Ohio State Board of Pharmacy formally approved the rules.

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?

Central Ohio is currently experiencing a mumps outbreak that has reached 323 cases, as reported by the Ohio Department of Health.¹ Nationally, there were 438 known mumps cases in 39 states last year, according to the Centers for Disease Control and Prevention.

In addition, a measles outbreak now has infected 42 people in six counties: Ashland, Coshocton, Holmes, Knox, Richland and Wayne.²

¹ <http://www.odh.ohio.gov/features/odhfeatures/Mumps.aspx>

² <http://www.odh.ohio.gov/features/odhfeatures/Measles%202014.aspx>

In response to these outbreaks, ODH and local health departments are encouraging residents to get vaccinated with the Measles-Mumps-Rubella (MMR) vaccine.

The spread of these two preventable diseases is largely attributed to unvaccinated populations. According to ODH State Epidemiologist Dr. Mary DiOrio, "Outbreaks of measles that we're seeing across the U.S. is more due to unvaccinated populations largely."³

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 in the interest of the public's health by providing enhanced access to this vaccine, 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 this rule package. It is the Board's responsibility to ensure that vaccinations performed by pharmacists are consistent throughout the state. It was the determination of the Board's Rule Review Committee 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 reviewed the Ohio Administrative Code to ensure that the regulation does 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 rule 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

³ <http://www.nbc4i.com/story/25400181/illnesses-previously-prevent-by-vaccinations-resurfacing-in-central-ohio>

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 rule impacts pharmacies and pharmacists who will opt to provide the MMR vaccine.

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).

Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license. This rule also requires pharmacists to meet the training criteria for vaccination courses.

c. Quantify the expected adverse impact from the regulation.

The proposed rule authorizes a licensed pharmacist to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older. The rule will require pharmacies offering the vaccine to update their protocols pursuant to OAC 4729-5-37, which may result in a negligible one-time cost.

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 pharmacists and pharmacies adhere to standards that protect the health and safety of all Ohioans. The recent outbreaks indicate the need to maximize the availability of the vaccine.

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 pharmacies that offer vaccinations and pharmacists who administer vaccinations.

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 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.

4729-5-38 IMMUNIZATION ADMINISTRATION

(A) In addition to the immunizations and medications listed in section 4729.41 of the Revised Code and pursuant to the requirements noted in section 4729.41 of the Revised Code and rules 4729-5-36 and 4729-5-37 of the Administrative Code, a pharmacist may administer ~~the zoster vaccine according to~~ the following vaccinations ~~requirements~~:

(A1) ~~the zoster vaccine according to~~ ~~The patient must meet~~ the age criteria specified in the F.D.A. approved labeling; and

(2) ~~the measles, mumps, and rubella (MMR) vaccine.~~

(B) The pharmacist must be able to document meeting the training criteria required by rule 4729-5-36.