



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Paula Steele, Common Sense Initiative Office

DATE: March 11, 2019

RE: **CSI Review – Pharmacists (OAC 4729:1-3-01 through 4729:1-3-04, 4729:1-5-02, 4729-5-25, 4729-5-36, 4729-5-37, 4729-5-38, 4729-5-39, and 4729-5-40)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of four new rules, one amended rule, and six rescinded rules proposed by the State of Ohio Board of Pharmacy (Board). The Board submitted the rule package to the CSI Office on May 4, 2018 and held the public comment period open through November 2, 2018. During that time, the Board received two comments and provided a response to comments on December 12, 2018.

The new rules outline the requirements for licensed pharmacists surrounding the administration of certain laboratory tests, immunizations, dangerous drugs, and naloxone. These rules include requirements involving pharmacist training and when a physician-approved protocol is necessary. The six rescinded rules from Ohio Administrative Code (OAC) Chapter 4729-5 cover the same subject matter, and the Board is incorporating the rescinded language into the new rules and into other portions of the OAC outside the current rulemaking. Amended rule OAC 4729:1-5-02 outlines the continuing education (CE) requirements for licensed pharmacists, and the Board proposes to amend the rule to align with the two-year licensing cycle.

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As part of the early stakeholder outreach process, the Board had the rule reviewed by their Rule Review Committee, which is composed of pharmacists from a number of practice settings. In addition, the rule was also reviewed and approved by the entire Board of Pharmacy. As a result of the outreach, the Board opted to waive the required naloxone patient training if the licensee had received the training within the last 12 months.

Two comments were received during the CSI public comment period. A representative of the National Association of Chain Drug Stores (Association) took issue with the requirement that courses on the administration of immunizations must be conducted by a provider that is accredited by the accreditation council for pharmacy education. The Board responded, citing the ubiquity of ACPE providers and the necessity of quality control that comes with accreditation. While the Board did not incorporate the suggestion, they opted to add a provision permitting individuals who completed immunization coursework prior to the rule's effective date to continue to provide vaccinations. In addition, the Association expressed concern over a perceived requirement for all pharmacy employees to receive training to dispense naloxone; the Board responded, clarifying that the requirement refers to the availability of naloxone, as opposed to its administration. Finally, the State Medical Board of Ohio submitted a comment requesting that the Board reinstate a provision of OAC 4729:1-3-04 regarding assessment and follow-up actions by a pharmacist. The Board responded that the initial inclusion of the provision was an accident, as it was meant for the immunization rule, adding that since dispensing naloxone occurs outside the pharmacy, pharmacist follow-up is not required. The Board indicates that a separate provision in the rule allows for physician instructions as needed.

The rules impact licensed pharmacists and the pharmacies that employ them. Licensed pharmacists may incur the monetary cost to obtain Clinical Laboratory Improvement Amendments (CLIA) certification at a rate of \$150 every 2 years in order to administer tests. In addition, Pharmacists must complete ACPE-accredited course, which can cost up to \$390, in order to administer immunizations. While there is currently no established coursework for the dangerous drugs training requirement, the Board estimates that the cost of an APCE-accredited course will similarly cost up to \$390. The BIA also notes that the rules require pharmacies to conduct initial and annual training on the availability of naloxone, and require pharmacists to complete required CE; the cost of both of these requirements can vary widely. The Board may institute administrative discipline for violation of the rules, including reprimand, suspension or revocation of a license, and monetary fines.

The BIA justifies the rules as necessary to protect the health and safety of the public, by enforcing uniform standards for the administration of laboratory tests, immunizations, dangerous drugs, and naloxone by licensed pharmacists. In addition, the Board asserts that regular CE coursework is

necessary.

Recommendation

Based on the information above, this office does not have any recommendations regarding this rule package.

Conclusion

The CSI Office concludes that the State of Ohio Board of Pharmacy should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.