CSI | Common Sense Initiative

MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Christopher Smyke, Regulatory Policy Advocate

DATE: October 26, 2017

RE: **CSI Review – Terminal and Wholesale Distributors of Dangerous Drugs (OAC 4729:5-2-02, 4729:5-3-04 and -05, 4729:5-12-01 and -02, 4729:6-3-04, 4729-5-29, and 4729-9-09)**

On behalf of Lt. Governor Mary Taylor, 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 eight rules submitted by the Ohio State Board of Pharmacy (Board). There are six new and two rescinded rules in this package. It was submitted to the CSI Office on August 8, 2017 and the comment period closed on August 28, 2017. One comment was received during this time.

The new rules establish protocols for on-site inspections of terminal and wholesale distributors of dangerous drugs by the Board. The rules also impose new licensing and renewal requirements for terminal distributors as well as requirements surrounding the release of confidential patient information. The new rules also define terms and establish licensure and regulatory requirements for licensees who provide medication therapy management. The rescinded rules established protocols for on-site inspections by the Board and requirements pertaining to confidential patient records; both rules were incorporated into Ohio Administrative Code (OAC) 4729:5-3-04, 4729:6-3-04, and 4729:5-3-05.

Prior to submission to the CSI Office, the rules were reviewed by the Board's Rule Review Committee, which is comprised of pharmacists from several practice areas. No input was received during early review of the draft rules. One comment was received during the CSI public comment period from a representative of the Ohio Veterinary Medical Association. The commenter offered several suggested changes regarding confidentiality of patient records to address issues unique to veterinary medicine. On October 17, the Board responded to CSI and the commenter that they made changes based on the suggestions.

The BIA indicates that the rules impact terminal and wholesale distributors of dangerous drugs, as well as pharmacists and interns providing medication therapy management. Violation of the rules may result in administrative discipline, including reprimand, suspension, or revocation of a license; submission of a corrective action plan; or monetary fines. The rules also place an administrative burden on terminal distributors to maintain consent forms and receipts for the release of confidential patient information. The license renewal fee for distributors can vary between $60 and $220, and the renewal application requires 30 minutes to complete. For licensees providing medication therapy management, the fee is $160 and the application takes 60 minutes to complete for a limited category II terminal distributor of dangerous drugs license with a medication therapy management classification.

The Board justifies these rules with the need to enforce uniform licensing standards, allow the Board to require a corrective action plan for distributors found in violation of the rules, protect confidential patient information, and to provide oversight of the practice of medication therapy management. After reviewing the proposed rules and BIA, the CSI Office has determined that the rule package satisfactorily meets the standards espoused by the CSI Office, and the purpose of the rule package is justified.

Recommendation
For the reasons explained above, the CSI office does not have any recommendations for this rule package.

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

cc: Emily Kaylor, Lt. Governor's Office