

**MEMORANDUM**

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Travis Butchello, Regulatory Policy Advocate

DATE: March 5, 2018

RE: **CSI Review – Terminal Distributors & Outpatient Pharmacies (OAC 4729:5-1-02, 4729:5-3-06, 4729:5-5-01 through 4729:5-5-14, 4729-5-15, 4729-9-17, 4729-9-02, 4729-5-09, 4729-5-27, 4729-5-13, 4729-5-16, 4729-5-18, 4729-5-20, 4729-5-22, 4729-5-21, 4729-5-24, 4729-5-26, 4729-5-19, 4729-5-10)**

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This rule package consists of sixteen new and fifteen rescinded rules proposed by the State of Ohio Board of Pharmacy. The rule package was submitted to the CSI Office on November 21, 2017 and the public comment period was held open through December 8. No comments were received during this time.

The new rules define who is a licensed health professional authorized to prescribe drugs in the State. Further, the rules provide requirements for storage of prescriptions, labeling, dispensing, and recordkeeping.

As part of the early stakeholder outreach process, the Board submitted the draft rules to its Rules Review Committee which is composed of pharmacists from a number of practice settings. After review, the draft rules were then approved by the entire Board. During the Committee's analysis,

they proposed numerous changes to the rules including extending the timeframe for when an original prescription may be destroyed and requiring the first and last name of the pharmacist conducting a prescription transfer. The Board chose to adopt all changes proposed by the Committee.

No comments were received during the CSI public comment period.

The rules impact pharmacists, pharmacy interns, and outpatient pharmacies that are licensed as terminal distributors of dangerous drugs. The Board notes in the BIA that violation of the rules will impose an adverse impact including suspension of a license, denial of a license, monetary fine, or complete revocation of a license. In addition, the rules will impose additional recordkeeping requirements, which will require administrative staff time to complete. Further, the BIA also states that there will be costs of compliance for additional requirements on the formatting for outpatient prescriptions and costs associated with obtaining the requisite permits. However, the Board emphasizes that the regulatory intent of the rules outweighs any adverse impact because the regulations protect public safety and ensure uniform standards of practice by pharmacies, pharmacists, and pharmacy interns.

Recommendation

For the reasons explained above, the CSI Office does not have any recommendations regarding this rule package.

Conclusion

Based on the above comments, 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.