



MEMORANDUM

TO: Cameron McNamee, Ohio Board of Pharmacy

FROM: Jacob Ritzenthaler, Regulatory Policy Advocate

DATE: November 7, 2017

RE: **CSI Review – Drug Destruction and Reporting Theft or Loss (OAC 4729-9-06, 4729-9-15, 4729:5-3-01, 4729:5-3-03, 4729:6-3-01, and 4729:6-3-03)**

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This rule package contains two rescinded rules and four new rules proposed by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on May 30, 2017 and the public comment period was held open through June 14, 2017. Two comments were received during this time.

The rules contained in this rule package concern the destruction of controlled substances and reporting requirements for the theft or loss of dangerous drugs. Ohio Administrative Code (OAC) 4729-9-06 and 4729-9-15 are being rescinded and replaced by new rules which draw distinctions between terminal distributors and other types of distributors, including wholesale distributors, manufacturers, outsourcing facilities, third-party logistics providers, and repackaging operations.

During early stakeholder outreach, the Board presented the rules to the Board of Pharmacy Rules Review Committee, which is made up of a variety of stakeholders in the pharmaceutical industry throughout the state. The Board accepted comments submitted by the committee and incorporated

77 South High Street | 30th Floor | Columbus, Ohio 43215-6117
CSIOhio@governor.ohio.gov

into the rule package. During the CSI public comment period, comments were received from two stakeholders. The first comment requested clarification on certain topics and offered suggestions for amending the rules, including allowing a pharmacy-approved nurse to supervise drug destruction, standardizing destruction requirements, and changing reporting parameters. The Board responded appropriately to these comments and amended the rules to reflect these suggestions. The Board stated that the drug destruction requirements were not amended since they intentionally mirror federal requirements. Another comment was received that suggested amending OAC 4729:5-3-03 to include a definition for the term “significant loss,” which was not defined within the rule. The Board accepted the suggestion and amended the rule to include the United States Drug Enforcement Agency’s definition.

The business communities impacted by these rules include long-term care facilities, terminal distributors of dangerous drugs, wholesale distributors of dangerous drugs, manufacturers of dangerous drugs, outsourcing facilities, third-party logistics providers, and repackagers of dangerous drugs. Adverse costs created by the rules include the time and staff necessary to adhere to drug destruction and reporting requirements, as well as penalties for violating the requirements of the rules, which can involve monetary fines and the suspension or revocation of a license. The BIA states that these rules help ensure public safety by ensuring that there are necessary safety measures for the disposal and loss of dangerous drugs and controlled substances. After reviewing the proposed rules and the BIA, the CSI Office has determined that the rules satisfactorily meet the standards espoused by the CSI Office, and the purpose of the rule package is justified.

Recommendations

For the reasons described above, the CSI Office has no recommendations on this rule package.

Conclusion

Based on its review of the proposed rule package, the CSI Office recommends the State of Ohio Board of Pharmacy should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.