



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Alexandra Simon, State of Ohio Board of Pharmacy

FROM: Ethan Wittkorn, Regulatory Policy Advocate

DATE: February 14, 2020

RE: CSI Review – Terminal Distributors of Dangerous Drugs (4729:5-5-19, 4729:5-9-19, 4729:5-3-17, 4729:5-3-18, 4729:5-9-20, 4729:5-5-20, 4729:5-4-02, 4729:5-35, 4729:5-28)

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 Board as provided for in ORC 107.54.

Analysis

This State of Ohio Board of Pharmacy (Board) rule package consists of seven new and two rescinded rules. It was submitted to the CSI Office on October 8, 2019, and the public comment period was open through October 25, 2019. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI office on October 8, 2019.

This rule package covers the requirements of terminal distributors of dangerous drugs. New rules in the package include requirements for central fill pharmacies, operation of an inpatient central fill pharmacy, automated pharmacy system operation, procedures for a terminal distributor in the event of a manufacturers recall, remote order processing of prescriptions for an institutional or outpatient pharmacy, and reporting on the termination or resignation of licensed or registered employees for specific reasons. The rescinded rules covered standards for automated drug delivery systems and central fill pharmacies, the content of which is being absorbed into new rules with updated filing numbers.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

During the period of early stakeholder outreach, the Board's Rules Review Committee (which is composed of pharmacists from various practice settings) reviewed the rule package. The Committee worked on the creation of the proposed rules and approved the package in its current form.

Numerous comments were submitted during the CSI public comment period that led to changes in automated pharmacy systems that set the quality assurance process to 45 days, authorized automated systems to replenish automated drug storage systems, set quality assurance tests to five percent of dispensed prescriptions, and allowed for the stocking of automated systems without pharmacist verification if bar code scanning is in place. Additional changes included an updated timeframe for the removal of a recalled drug from inventory, additional language on termination or resignations that must be reported to the Board to be limited to those resulting from errors in dispensing due to reckless or unprofessional conduct, and additional language regarding a licensee's duty to report anything directly observed or objective evidence regarding errors in dispensing that lead to resignation or termination.

Lastly, the Board made changes to central fill pharmacy requirements for clarification to specify responsible parties for patient counseling requirements, requirements for prescription labeling, and permission for a central fill pharmacy to return drugs to stock. Commenters included OhioHealth Mercy Health, Nationwide Children's Hospital, Premier Health, Kroger, Cleveland Clinic, UC Health, and CVS Health.

The impacted communities of the proposed rules include all Ohio terminal distributors of dangerous drugs. Potential adverse impacts that the distributors will experience include administrative discipline if the rules are violated. Discipline could include reprimand, license suspension or revocation, and monetary fines. In addition, there are administrative costs associated with the development of procedures to meet record keeping and labeling requirements, frequent reviews of automated pharmacy systems, the development of written policies regarding drug recalls, quarantining of drugs under recall, meeting notification requirements for some terminated or resigning employees, and training expenses related to remote medication order processing.

The Board states that the rules are necessary to promote public safety by ensuring uniform standards for pharmacy practice and the distribution of drugs and make pharmacists accountable for the care they provide. Additionally, the rules protect the public by requiring distributors to report of the termination of employees for actions that may cause a danger to the public and ensure that recalled drugs are not dispensed.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.