



# Common Sense Initiative

Mike DeWine, Governor  
Jon Husted, Lt. Governor

Joseph Baker, Director

## MEMORANDUM

**TO:** Summer Corson, State of Ohio Board of Pharmacy

**FROM:** Caleb White, Business Advocate

**DATE:** April 15, 2024

**RE:** **CSI Review – Terminal Distributors and Drug Distributors (OAC 4729:5-3-23, 4729:5-5-18, 4729:5-2-03, 4729:5-2-04, and 4729:5-2-05)**

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This rule package consists of three new rules, two amended rules, and two rescinded rules proposed by the State of Ohio Board of Pharmacy (Board) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on March 7, 2024, and the public comment period was held open through March 29, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on March 7, 2024.

Ohio Administrative Code (OAC) 4729:5-2-03 sets forth the requirements for when a terminal distributor of dangerous drugs changes its ownership, business name, category, or address. This rule is to be rescinded and replaced with a rule of the same number. The new rule addresses the same topics as the rescinded rule but reformats the rule, separates the requirements in the rule by the type of business, further clarifies what constitutes a publicly traded company, defines what constitutes a change of address, and adds a requirement related to notifying the board of a change of address. OAC 4729:5-2-04 establishes the requirements and procedure for the discontinuation of business as a terminal distributor of dangerous drugs. This rule is amended to change the timeline for when a

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terminal drug distributor is required to notify the Board of its discontinuation of business from thirty days prior to within thirty days and to add the requirement for a terminal distributor of dangerous drugs to notify each patient it has filled a prescription for, add list of information to be included in this notice, and require this notice to be made a minimum of fifteen calendar days prior to closing. OAC 4729-2-05 sets forth the requirements when a distributor of dangerous drugs changes its ownership, business name, category, or address. This rule is to be rescinded and replaced with a rule of the same number. The new rule addresses the same topics as the rescinded rule but reformats the rule, separates the requirements in the rule by the type of business, further clarifies what constitutes a publicly traded company, defines what constitutes a change of address, and adds a requirement related to notifying the board of a change of address. OAC 4729:5-3-23 is a new rule which establishes the procedure and requirements surrounding operating a mobile clinic or medication unit that administers prescription medications and devices. OAC 4729:5-5-18 allows pharmacists at outpatient pharmacies to provide a patient with a customized patient medication package rather than dispensing two or more dangerous drugs in their own separate container and establishes the requirements for dispensing such packages. This rule is amended to increase the medication supply permitted to be dispensed through these packages from a maximum of a thirty-one-day supply to a ninety-day supply.

During early stakeholder outreach, the Board distributed the rules to all of its licensees and registrants for public comment. The Board received ten comments during this period which suggested changing the medication packages dispensed at once from a thirty-one-day supply to a ninety-day supply in OAC 4729:5-5-18 and one comment asking for an exception to a non-profit requirement for entities that provide treatment for mental health and substance use disorder in OAC 4729:5-3-23. The Board accepted both suggestions and implemented them into the proposed rules. No comments were received during the CSI public comment period.

The business community impacted by the rules includes drug distributors and terminal distributors of dangerous drugs. The adverse impacts created by the rules include licensure application fees (\$160 to \$220 annually), the application fees for a change in ownership (\$1,900 to \$2,000 biennially), the time associated with completing applications, and the costs associated with labeling, packaging notification, reporting, oversight, and record keeping requirements. Additionally, the Board notes that a violation of these rules may result in discipline for the licensee which can include reprimand, fines, the suspension of a license and the revocation of a license. The Board estimates that the license application for a terminal distributor of dangerous drugs takes thirty to sixty minutes to complete, the application for a change in ownership, business name, category, or address of a drug distributor takes one to two hours, the discontinuation of business notification form takes approximately ten minutes to complete, inventory may take several hours to complete, and patient notification that a location is shutting down will depend on the number of patients served at that location. The Board states that the adverse impacts to business are justified to protect and promote public safety through ensuring

uniform standards for the operation of terminal distributors of dangerous drugs.

### **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.