



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

TO: Summer Corson, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: March 7, 2024

RE: **CSI Review – Terminal Distributors (OAC 4729:5-1-02, 4729:5-3-01, 4729:5-3-03, 4729:5-3-05, 4729:5-3-06, 4729:5-3-07, 4729:5-3-08, 4729:5-3-10, 4729:5-7-01, 4729:5-7-02, 4729:5-7-03, 4729:5-7-04, 4729:5-7-05, 4729:5-12-01, 4729:5-12-02)**

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 eleven amended rules and four no-change 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 February 13, 2024, and the public comment period was held open through February 29, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on February 13, 2024.

Ohio Administrative Code (OAC) 4729:5-1-02 identifies the licensed health professionals who are authorized to prescribe drugs or dangerous drugs. The rule is amended to update grammar. OAC 4729:5-3-01 provides for the disposal of controlled substances by a terminal distributor of dangerous drugs. The rule is amended to update language and grammar, add clarifying language, and update the effective dates of cited federal regulations. OAC 4729:5-3-03 provides for inspections carried out by the Board and corrective actions taken by licensees to remedy violations. The rule is amended to update language. OAC 4729:5-3-05 provides for the confidentiality of patient records. The rule is

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amended to update grammar. OAC 4729:5-3-06 establishes requirements for the storage of adulterated drugs. The rule is amended to update grammar. OAC 4729:5-3-07 requires all category III terminal distributors to complete a controlled substances inventory pursuant to federal regulations. OAC 4729:5-3-08 contains requirements for terminal distributors who sell dangerous drugs online. The rule is amended to update language and grammar as well as add clarifying language. OAC 4729:5-3-10 prohibits terminal distributors from employing an individual with a felony conviction if the position allows access to controlled substances. The rule is amended to update the effective date of a cited federal regulation.

OAC 4729:5-7-01 contains definitions pertaining to charitable pharmacies. OAC 4729:5-7-02 requires a pharmacy seeking authorization to be a charitable pharmacy to obtain licensure as a terminal distributor of dangerous drugs. The rule is amended to update grammar. OAC 4729:5-7-03 describes who may transfer an eligible sample drug to a charitable pharmacy. The rule is amended to permit the donation of a sample drug to a drug repository program. OAC 4729:5-7-04 establishes eligibility requirements for sample drugs received by a charitable pharmacy. OAC 4729:5-7-05 establishes requirements for the dispensing of sample drugs by a charitable pharmacy. OAC 4729:5-12-01 contains definitions pertaining to medication therapy management. The rule is amended to update grammar. OAC 4729:5-12-02 specifies requirements for pharmacists and pharmacy interns who provide medication therapy management. The rule is amended to update language and grammar.

During early stakeholder outreach, the Board distributed the rules to all of its licensees and registrants for public comment. The Board did not receive any comments from stakeholders. No comments were received during the CSI public comment period.

The business community impacted by the rules includes terminal distributors of dangerous drugs. The adverse impacts created by the rules include the time and costs associated with completing applications, obtaining licensure, maintaining records, following proper procedures, complying with inspections, and administrative licensure discipline for a violation of the rules. Discipline may include reprimand, monetary fine, and/or suspension or revocation of a license. The Board notes costs of \$160-\$220 annually for licensure as a terminal distributor of drugs, \$5,000-\$8,000 for an application for accreditation, and \$160 for licensure as a category II terminal distributor of dangerous drugs with a medication therapy management classification. Additionally, the Board estimates that it takes thirty to sixty minutes to complete an application for licensure. The Board states that the adverse impacts to business are justified to comply with federal regulations, implement statutory requirements, and protect and promote public safety.

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.