Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

MEMORANDUM

TO: Summer Reyburn, State of Ohio Board of Pharmacy

FROM: Caleb White, Business Advocate

DATE: November 15, 2024

RE: **CSI Review – FYR 2024 Terminal Distributors of Dangerous Drugs (OAC 4729:5-3-04, 4729:5-3-09, 4729:5-8-01, 4729:5-8-02, 4729:5-10-01, 4729:5-10-02, 4729:5-10-03, 4729:5-10-05, 4729:5-10-06, 4729:5-17-01, 4729:5-17-02, 4729:5-17-03, 4729:5-17-04, and 4729:5-17-05)**

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 six amended rules and eight 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 October 15, 2024, and the public comment period was held open through November 1, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on October 15, 2024.

Ohio Administrative Code (OAC) 4729:5-3-04 establishes license verification requirements for terminal distributors of dangerous prior to the sale of dangerous drugs. This rule is amended to exempt certain transfers of drugs for emergency medical services and for intracompany transfers made under OAC 4729:5-3-09 as well as to update punctuation and language. OAC 4729:5-3-09 establishes the definitions and requirements for the occasional sale and transfer of dangerous drugs. This rule is amended to exempt local health departments from the requirement to become licensed as

a terminal distributor of dangerous drugs under certain conditions as well as to add definitions and references to statute and other provisions of this rule.

OAC 4729:5-8-01 establishes definitions related to non-resident pharmacies. OAC 4729:5-8-02 establishes the requirements to become licensed as a nonresident terminal distributor of dangerous drugs. OAC 4729:5-10-01 establishes the definitions related to drug repository programs. OAC 4729:5-10-02 establishes the requirements a pharmacy, hospital, or nonprofit must meet to be eligible to participate in a drug repository program. OAC 4729:5-10-03 establishes who may donate drugs to a pharmacy, hospital, or nonprofit clinic that elects to participate in a drug repository program and the requirements for the donation of drugs. OAC 4729:5-10-05 establishes who is eligible to receive drugs from drug repository program. OAC 4729:5-10-06 establishes the forms and information that must be submitted by drug donors and recipients of drugs from a drug repository program and establishes records retention requirements.

OAC 4729:5-17-01 establishes the definitions related to medical oxygen, nitrous oxide, medical gasses, and dialysis solutions. OAC 4729:5-17-02 establishes requirements related to the sale, storage, labeling, and use of medical oxygen. This rule also contains requirements for reporting and records retention for medical oxygen. This rule is amended to add a statutory and rule reference. OAC 4729:5-17-03 establishes requirements related to the sale and storage of nitrous oxide. This rule also contains requirements for reporting and records retention for medical oxygen. This rule is amended to add a statutory and rule reference, eliminate unnecessary language, and to update records retention requirements. OAC 4729:5-17-04 establishes requirements related to the possession or sale of compressed medical gasses and includes records retention requirements, reporting requirements, documentation requirements, and training requirements for those that fill containers with compressed medical gasses. This rule also contains requirements for employees of firms that own cryogenic vessels. This rule is amended to clarify that this rule is applicable to medical oxygen and nitrous oxide and to add a statutory reference. OAC 4729:5-17-05 establishes requirements related to the sale and storage of dialysis solutions. This rule also contains requirements for reporting and records retention for dialysis solutions. This rule is amended to add a statutory reference.

During early stakeholder outreach, the Board distributed the rules to stakeholders for public comment. No comments were received during this period or during the CSI public comment period.

The business community impacted by the rules consists of terminal distributors of dangerous drugs. The adverse impacts created by the rules are license validation requirements, monitoring requirements, licensure requirements, notification requirements, the costs associated with developing eligibility requirements, recordkeeping requirements, and the time needed to complete applications. The Board notes that the license fee for a distributor of dangerous drugs ranges from $160 to $220 annually and that the license fee for a wholesale distributor of dangerous drugs is $950 annually. The

Board further notes that license applications take between thirty to sixty minutes to complete, notification requirements take approximately five minutes to complete and the time to confirm a licensed entity takes approximately one to two minutes. The Board does highlight several changes that will reduce the adverse impacts to business. These include changes to the requirements for licensure verification for EMS and intracompany transfers and allowing local health departments to conduct occasional wholesale sales of dangerous drugs to other health departments. The Board states that the adverse impacts are justified to protect and promote public safety by ensuring uniform standards for the practice of pharmacy or the preparation/distribution 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.