



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 – Drug Distributors (OAC 4729:6-2-03, 4729:6-2-04, 4729:6-2-06, 4729:6-3-01, 4729:6-3-03, 4729:6-3-04, 4729:6-3-05, 4729:6-3-06, 4729:6-3-07, 4729:6-3-08, 4729:6-5-01, 4729:6-5-02, 4729:6-6-01, 4729:6-7-01, 4729:6-8-01, 4729:6-8-02, 4729:6-9-01, 4729:6-9-02, 4729:6-10-01, 4729:6-10-02, 4729:6-11-01, and 4729:6-11-02)**

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 twenty-two amended 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) 4729:6-2-03 requires criminal records checks for certain individuals prior to issuing a distributor of dangerous drug license. The rule is amended to update language, update the name of the Ohio Bureau of Criminal Investigation (BCI), require criminal records checks for all members of a limited liability company, remove the requirement for the agency director of a government agency, and clarify that the requirement applies to the executive director or

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

CSIPublicComments@governor.ohio.gov

any equivalent position of a nonprofit organization. OAC 4729:6-2-04 specifies the information that must be provided on an application for a license as a distributor of dangerous drugs. The rule is amended to update language, remove a prohibition on the trade or business name being similar to another distributor, incorporate limited liability companies and nonprofit organizations, prohibit the Board from licensing an entity outside the United States, and require all applicants except manufacturers engaged in the distribution of dangerous drugs to obtain all applicable licenses. OAC 4729:6-2-06 sets forth the procedure for discontinuing business as a distributor of dangerous drugs. The rule is amended to add clarifying language, update typography, and clarify that notice must be filed with the Board within thirty days of discontinuation of business.

OAC 4729:6-3-01 requires licensees to follow federal regulations for disposing of controlled substance dangerous drugs. The rule is amended to update the effective dates of cited federal regulations and extend the required recordkeeping period from three years to five years. OAC 4729:6-3-03 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 4729:6-3-04 requires a drug distributor to verify the licensure of a prospective purchaser or seller prior to selling or purchasing dangerous drugs. The rule is amended to update language and extend the required recordkeeping period from three years to five years. OAC 4729:6-3-05 requires drug distributors to report suspicious orders to the Board. The rule is amended to update language, citations, and grammar, clarify what is not considered a reported drug, and remove an outdated provision requiring drug distributors to report certain information. OAC 4729:6-3-06 requires all category III drug distributors to complete a controlled substances inventory pursuant to federal regulations. The rule is amended to update grammar and extend the required recordkeeping period from three years to five years. OAC 4729:6-3-07 contains requirements for drug distributors who sell dangerous drugs online. The rule is amended to update language and add clarifying language. OAC 4729:6-3-08 provides for the sale and distribution of drug samples and complimentary supplies. The rule is amended to update grammar and clarify that certain prescribers may be exempt from licensure.

OAC 4729:6-5-01 specifies requirements regarding general operations for wholesale distributors of dangerous drugs. The rule is amended to update language, citations, typography, and grammar, add clarifying language, remove unnecessary language, and extend the required recordkeeping period from three years to five years. OAC 4729:6-5-02 contains recordkeeping requirements for wholesale distributors of dangerous drugs. The rule is amended to update language and grammar. OAC 4729:6-6-01 specifies requirements regarding general operations for wholesale distributors of dangerous drugs with a virtual classification. The rule is amended to update language and grammar, add clarifying language, remove unnecessary language, and extend the required recordkeeping period from three years to five years. OAC 4729:6-7-01 specifies requirements regarding general operations for wholesale distributors of dangerous drugs with a broker classification. The rule is amended to update language and grammar, remove unnecessary language, and state that an entity engaged in the

brokering of dangerous drugs solely for the purpose of reverse distribution does not need to obtain a license as a wholesale distributor of dangerous drugs with a broker classification. OAC 4729:6-8-01 specifies requirements regarding general operations for manufacturers of dangerous drugs. The rule is amended to update language, citations, typography, and grammar, add clarifying language, remove unnecessary language, and extend the required recordkeeping period from three years to five years. OAC 4729:6-8-02 contains recordkeeping requirements for manufacturers of dangerous drugs. The rule is amended to update language and grammar.

OAC 4729:6-9-01 specifies requirements regarding general operations for repackagers of dangerous drugs. The rule is amended to update language, citations, typography, and grammar, add clarifying language, remove unnecessary language, and extend the required recordkeeping period from three years to five years. OAC 4729:6-9-02 contains recordkeeping requirements for repackagers of dangerous drugs. The rule is amended to update language, grammar, and typography. OAC 4729:6-10-01 specifies requirements regarding general operations for outsourcing facilities. The rule is amended to update language, citations, typography, and grammar, add clarifying language, remove unnecessary language, and extend the required recordkeeping period from three years to five years. OAC 4729:6-10-02 contains recordkeeping requirements for outsourcing facilities. The rule is amended to update language and grammar. OAC 4729:6-11-01 specifies requirements regarding general operations for third-party logistics providers. The rule is amended to update language, citations, typography, and grammar, add clarifying language, remove unnecessary language, and extend the required recordkeeping period from three years to five years. OAC 4729:6-11-02 contains recordkeeping requirements for third-party logistics providers. 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 received questions regarding the necessity of the required recordkeeping period from three years to five years. The Board noted that this requirement was set in statute. No comments were received during the CSI public comment period.

The business community impacted by the rules includes Ohio-licensed drug distributors such as wholesalers, manufacturers, third-party logistics providers, outsourcing facilities, and repackagers. The adverse impacts created by the rules include the time and costs associated with undergoing criminal records checks, completing applications, following proper procedures, complying with inspections, verification of licensure, reporting information, maintaining records, 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 that the cost of a criminal records check with both the BCI and the Federal Bureau of Investigation is \$61.70 combined. Additionally, the Board estimates that it takes thirty to sixty minutes to complete an application, five to ten minutes to submit a discontinuation of business form, thirty seconds to confirm licensure using Ohio's

eLicensing system, and fifteen minutes to complete and submit notification of off-site storage. The Board points out that the changes to the rules exempt the reporting of certain schedule I and II chemicals from suspicious order monitoring and exempt drug distributors engaged in brokering dangerous drugs for the purpose of disposal from licensure requirements. 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.