

Common Sense Initiative

> Mike DeWine, Governor Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

TO:	Summer Reyburn, State of Ohio Board of Pharmacy
FROM:	Jacob Ritzenthaler, Business Advocate
DATE:	November 15, 2024
RE:	CSI Review – Controlled Substances (OAC 4729:9-3-01 through 4729:9-3-08)

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.

<u>Analysis</u>

This rule package consists of eight rescinded rules and one new rule proposed by the Ohio Board of Pharmacy (Board) as part of the statutory five-year review process.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) Chapter 4729:9-3 establishes requirements related to the control of ephedrine. OAC 4729:9-3-01 through 4729:9-3-08 are proposed for rescission and the provisions of each rule are incorporated in new rule OAC 4729:9-3-01. The rule contains provisions for licensure of businesses that manufacture, sell, dispense, or import/export ephedrine products, drug security and storage, inventory, record keeping, product exemption, and exceptions

During early stakeholder outreach, the Board sent the proposed rules to industry stakeholders for feedback and reviewed the rules during Board meetings. No comments were received during that time or during the CSI public comment period.

The business community impacted by the rules includes all businesses that purchase or possess

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ephedrine products. The adverse impacts created by the rules include the application process for licensure as a terminal distributor of dangerous drugs, as well as the cost of licensure fees and maintaining records. The annual cost of a terminal distributor license is \$220, and applications are estimated to take a business up to two hours to complete. The Board states that the adverse impacts are necessary to comply with statute and ensure the safe distribution and handling of controlled substances.

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.