



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Alexandra Simon, State of Ohio Board of Pharmacy

FROM: Ethan Wittkorn, Regulatory Policy Advocate

DATE: January 13, 2020

RE: CSI Review – Drug Distributor Record Keeping (4729:6-3-08, 4729:6-5-02, 4729:6-6-01, 4729:6-7-01, 4729:6-8-02, 4729:6-9-02, 4729:6-10-02, 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 State of Ohio Board of Pharmacy (Board) rule package consists of eight amended rules. It was submitted to the CSI Office on November 5, 2019, and the public comment period was open through November 22, 2019. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI office on November 5, 2019.

This rule package covers the Board's recordkeeping requirements for licensed drug distributors in Ohio. Amendments to the rules include a requirement that records be maintained for five years for the sale or distribution of complimentary supplies and drug samples, wholesale distributors of dangerous drugs, virtual wholesale distributors, brokers, manufacturers, repackagers, outsourcing facilities, and third-party logistics providers.

During the period of early stakeholder outreach the Board distributed the proposed rules to all Ohio licensed drug distributors and posted them to the Board's website. During both the early stakeholder outreach period and the CSI public comment period, the Board received no feedback.

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Impacted communities include all Ohio licensed drug distributors including wholesalers, manufacturers, third party logistics providers, outsourcing facilities, and repackagers. Potential impacts include administrative discipline for violating the rules, which may include reprimand, denial or suspension of a license, monetary fines, and revocation of a license. In addition, there are administrative costs associated with the maintenance and storage of records for a five-year period and a requirement that those using an offsite storage facility file a one-page form to notify the Board. The Board states that drug distributors operating in 20 other states must already maintain records for five years. The Board states that the rules are necessary to protect and promote public safety by ensuring licensees maintain sufficient records in order for the Board to conduct thorough investigations of any violations of the law or regulations.

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.