



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: June 26, 2020

RE: CSI Review – Non-Resident Terminal Distributor of Dangerous Drugs (OAC 4729:5-3-08)

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.

Analysis

This State of Ohio Board of Pharmacy (Board) rule package consists of one amended rule. It was submitted to the CSI Office on January 17, 2020, and the public comment period was open through February 10, 2020. Unless otherwise noted below, this recommendation reflects the version of the proposed rule filed with the CSI Office on January 17, 2020.

The proposed rule covers inspection and labeling requirements for non-resident terminal distributors of dangerous drugs. Amendments to the rule are being proposed to clarify requirements. Older versions of the rule only state that non-resident terminal distributors must comply with all applicable statutory and regulatory mandates, and the proposed updates specify what the applicable mandates are. The Board stated that all of the newly-specified requirements were previously found in other rules.

During the period of early stakeholder outreach, the proposed rule was shared with all Ohio licensed drug distributors in addition to being posted publicly on the Board's website. During the early stakeholder outreach period, one comment was submitted by CVS Health. As a result of CVS

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Health's comment, the Board made additions to the rule to clarify that non-resident licensees may dispense medications prescribed by a non-resident prescriber, language changes to reflect that out-of-state licensees will not be penalized for requirements of their home state that conflict with those of Ohio, and the removal of expiration date requirements for transfer of sale records. Additionally, CVS Health made a comment during the CSI public comment period suggesting additional language to records and labeling requirements to allow records to include what a patient or owner provides, and the legal or contractual name of a business. The Board shared their response to comments with CSI on June 16, 2020, and the suggestions of CVS Health were adopted to the rule.

Impacted communities include all non-resident terminal distributors of dangerous drugs. Adverse impacts include a potential for administrative discipline for a failure to comply with the proposed rule, as well as the administrative costs and time to comply with requirements in the rule such as labeling, record keeping, and inspection procedures. However, the Board states that most pharmacies can currently meet the specified labeling and record keeping requirements. The Board also states that the proposed rule is necessary to protect the health and safety of Ohioans by providing uniform regulations for drug dispensing pharmacies.

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.