



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Sean McCullough, Director

MEMORANDUM

TO: Alexandra Simon, State of Ohio Board of Pharmacy

FROM: Ethan Wittkorn, Regulatory Policy Advocate

DATE: June 23, 2021

RE: CSI Review – Reporting Theft or Loss of Dangerous Drugs (OAC 4729:5-3-02 and 4729:6-3-02)

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 two amended rules and two new rules. It was submitted to the CSI Office on April 27, 2021, and the public comment period was open through May 14, 2021. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on April 27, 2021.

The rules proposed in this package set notification requirements for terminal and wholesale distributors of dangerous drugs when a theft or significant loss of a dangerous drug occurs. The proposed rules have been amended to update references to applicable federal codes and forms.

During the early stakeholder outreach period, the Board posted notice of the proposed rule revisions to their website with a request for input. No comments were received as a result. However, during the CSI public comment period, one comment was received by the Ohio Association of Ambulatory Surgical Centers. The Board responded to this comment on June 24, 2021, by incorporating U.S. Drug Enforcement Agency guidance to help affected parties better understand what constitutes a significant loss.

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Terminal distributors of dangerous drugs, drug manufacturers, parties responsible for transporting dangerous drugs, and wholesale distributors of dangerous drugs may be impacted by the proposed rules. A violation of the proposed rules may result in discipline for a licensee of the Board, which may affect their license. Further potential impacts include administrative costs associated with the required reporting of a loss or theft of dangerous drugs under the care of an affected party. The proposed rules help to ensure the safety of the public by applying uniform standards on the reporting of missing dangerous drugs and 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.