

**MEMORANDUM**

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Sydney King, Regulatory Policy Advocate

DATE: July 7, 2016

RE: **CSI Review – Dangerous Drugs (OAC 4729-9-28 and 4729-9-09)**

On behalf of Lt. Governor Mary Taylor, 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 Agency as provided for in ORC 107.54.

Analysis

This Ohio State Board of Pharmacy (Board) rule package consists of one rescinded and one amended rules. This rule package was submitted to the CSI Office on May 11, 2016, with the comment period ending May 24, 2016. The package initially included Rule 4729-16-01, but as a result of stakeholder feedback during the CSI public comment period, the Board has removed the rule and will resubmit it to CSI after addressing stakeholder concerns.

The rule package provides regulations for virtual wholesale distributors of dangerous drugs¹ and the security and control of dangerous drugs. Rule 4729-9-09 requires prescribers to provide security and control for prescription blanks and Drug Enforcement Administration (D.E.A.) controlled substance forms. The rule is being rescinded, as the language was incorporated into Rule 4729-9-11, which the CSI Office reviewed on March 1, 2016. Rule 4729-9-28 is being amended to remove the requirement that virtual wholesalers have a D.E.A. license. The BIA states that virtual wholesalers do not possess controlled substances and therefore, a D.E.A. license is not necessary.

¹ A virtual wholesale distributor is a person engaged in the wholesale distribution of dangerous drugs who has title but does not take physical possession of the dangerous drugs.

According to the BIA, the Board had initially reviewed the rules to comply with the statutory five-year rule review in 2015. During the review, the Board reached out to a representative group of stakeholders including several providers and pharmacies. The BIA states that the feedback from the rule review committee was incorporated into the rule package. Two comments were received during the CSI public comment period, both related to Rule 4729-16-01 which was subsequently removed from the package.

The Board identifies Ohio licensed pharmacists, virtual wholesalers of dangerous drugs and licensed prescribers of controlled substance as the impacted industries. The BIA states that violation of the rules may result in criminal charges. The Board estimates the amendments will clarify and reduce the impacts on the business community

After reviewing the proposed rules and BIA, the CSI Office determined that the rule package satisfactorily meets the standards espoused by the CSI Office, and the purpose of the rules justifies the adverse impacts identified in the BIA.

Recommendations

For the reasons described above, the CSI Office has no recommendations regarding this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Board should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.

cc: Mark Hamlin, Lt. Governor's Office