

**MEMORANDUM**

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Sophia Papadimos, Regulatory Policy Advocate

DATE: September 11, 2015

RE: **CSI Review – Dangerous Drugs (OAC 4729-9-28, 4729-9-29, 4729-9-27, 4729-9-18, 4729-9-20, 4729-9-07 and 4729-9-03)**

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 seven rules (three new rules, one amended rule, and three no-change rules). The rule package was submitted to the CSI Office on July 27, 2015 and the public comment period was held open through August 11, 2015. No comments were received during this time.

The proposed rules in this package pertain to distributors of dangerous drugs. Ohio Administrative Code (OAC) 4729-9-27 is a new rule being proposed in response to federal requirements that prohibit a terminal distributor or wholesale distributor of dangerous drugs that possess controlled substances from employing someone who has been convicted of a felony drug crime or administrative action by the United States Drug Enforcement Administration (DEA). OAC 4729-9-28 and OAC 4729-9-29 specify requirements for licensure as a wholesale distributor of dangerous drugs for virtual wholesale distributors/brokers and third party logistics providers.¹ The

¹ A third party logistics provider contracts with a manufacturer or wholesale distributor of dangerous drugs to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not have general responsibility to direct the dangerous drug's sale or disposition.

Board explained that these are new business types that previous rules did not account for and therefore, new rules need to be created. OAC 4729-9-18 requires all locations licensed with the Board to maintain the license at that site and is being amended to correct a typo. The rules being proposed without changes are being reviewed pursuant to the five-year review requirement in statute and outline the procedures for discontinuing business as a wholesale or terminal distributor of dangerous drugs; labeling and recordkeeping requirements for drugs that are repackaged or relabeled by pharmacies; and provide minimum standards for first-aid departments that stores dangerous drugs.

The proposed rules were reviewed and approved by the Board's Rule Review Committee. The committee is comprised of different stakeholders, including Walmart, OhioHealth, Nationwide Children's Hospital, Central Ohio Compounding Pharmacy, Cedarville University School of Pharmacy, and others. The BIA submitted by the Board describes the adverse impact of the rules in detail. No comments were received that requirements are overly burdensome.

After reviewing the proposed rules and associated BIA, the CSI Office has determined that the rule package satisfactorily meets the standards espoused by the CSI Office, and the purpose of the rules is justified.

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