

**MEMORANDUM**

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: July 2, 2018

RE: **CSI Review – Nonresident Terminal Distributors (OAC 4729:5-8-01, 4729:5-8-02, 4729:5-8-03, 4729-10-01, 4729-10-02, 4729-10-03, and 4729-10-04)**

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This rule package consists of four rescinded rules and three new rules submitted by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on May 7, 2018 and the public comment period closed on May 25, 2018. No comments were received during this time.

The rules being rescinded require each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio to obtain a terminal distributor of dangerous drugs license. The proposed rules mirror this requirement, but no longer allow for inspections by entities other than the Pharmacy Board. Nonresident terminal distributors are subject to inspections by the Board; previously, inspections conducted by in-state authorities could be used in lieu of an inspection by the Board. The proposed rules do not implement a federal requirement; the Board states that the regulation of dangerous drugs and the pharmacy profession has traditionally been done at the state level. ORC 4729.26 gives the Board authority to adopt rules governing the distribution of dangerous drugs, to ensure that the practice of pharmacy and the dispensing of dangerous drugs are consistent throughout the state.

77 South High Street | 30th Floor | Columbus, Ohio 43215-6117
CSIOhio@governor.ohio.gov

As part of early stakeholder outreach, the Board distributed the rule package for initial public comment by posting it on the Board's proposed rules website. The Board received feedback concerning penalties to nonresident pharmacies when compliance with the rules would cause the pharmacy to violate statutory or regulatory requirements in the state in which it is located. Ohio Administrative Code (OAC) 4729:5-8-03 was amended to permit the acceptance of inspections conducted by non-state entities in lieu of on-site inspections conducted by Board agents, and language was changed to ensure that pharmacies would not be penalized for complying with the laws of its home state where there is a conflicting Ohio regulation. The rule package as submitted to CSI reflects all stakeholder concerns raised during early outreach, and there were no comments received during the CSI public comment period.

The rules impact all nonresident terminal distributors of dangerous drugs. All nonresident terminal distributors that sell dangerous drugs at retail in the state of Ohio must obtain a license. This includes any entity located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio. Licensure as a terminal distributor of dangerous drugs costs between \$120 and \$220 annually, and the license application takes 30-60 minutes to complete. Once a license is issued, a nonresident terminal distributor becomes subject to on-site inspections by the Board. Costs associated with this provision stem from the administrative costs required to comply with this provision, including compliance with Ohio regulations for compounding dangerous drugs and dispensing controlled substance medications.

Violations of the rules may result in administrative licensure discipline. This includes reprimand, denial of a license, suspension of a license, monetary fines, and revocation of a license. The Board states that any adverse impact is justified because the regulations are intended to protect and promote public safety. It emphasizes that the rules serve to ensure uniform regulations to protect the health and safety of Ohioans by providing uniform regulations for pharmacies dispensing medications into the state.

Recommendation

For the reasons explained above, the CSI office does not have any recommendations for this rule package.

Conclusion

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