

**MEMORANDUM**

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Tess Eckstein, Regulatory Policy Advocate

DATE: September 7, 2016

RE: **CSI Review – Licensure Amendments (OAC 4729-9-08, 4729-9-16, 4729-9-28, and 4729-9-29)**

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 amended rules being proposed by the State of Ohio Board of Pharmacy. The rule package was submitted to the CSI Office on August 1, 2016, and the comment period remained open until August 19, 2016. No comments were submitted during this time.

Rule 4729-9-08 requires a new application, required fee, and license for any change of ownership, business or trade name, category, or address of a terminal or wholesale distributor (including virtual wholesalers and third party logistics providers) of dangerous drugs. Amendments are being proposed to clarify what a change of ownership includes and does not include. Rules 4729-9-16, 9-28 and 9-29 specify minimum requirements for wholesalers, virtual wholesalers (i.e. virtual wholesale distributors and brokers), and third party logistics providers, respectively. Each of these three rules is being amended to specify required information to be included on an application, as well as the individuals who are subject to background checks.

This rule package impacts virtual wholesalers, terminal distributors, wholesale distributors, and third party logistics providers of dangerous drugs. In designating adverse impacts for these rules, the State Board of Pharmacy noted in the BIA that violation of the rules could result in administrative licensure discipline, such as reprimand, suspension of a license, monetary fine,

and/or revocation of a license. It also acknowledged the minimal amount of time it takes to complete a license (or renewal) application, as well as the cost of licenses. The cost of a terminal distributor license ranges from \$112.50 to \$150, while the three other licenses range in price from \$750 to \$787.50. Finally, the cost of each background check per officer of the company is \$22 for a check from the Ohio Bureau of Criminal Identification and Investigation, \$24 for a check from the Federal Bureau of Investigation, and some agencies may charge a processing fee of up to \$40. In completing its review, the CSI Office also identified the following adverse impacts: record keeping, report filing, and filling out forms to comply with requests from the Board.

The BIA explains that these adverse effects are justified because the regulations are essential to protecting public health and safety by ensuring the safe and effective licensure of entities distributing dangerous drugs. For the Board to provide this protection, it must retain updated information in the event of any significant operational change, and ensure that those with access to a significant quantity of dangerous drugs are subject to background checks. These actions help increase public safety and uniformity of drug distribution in Ohio. Furthermore, providing clarity as pertains to licensing requirements leads to fewer delays in the licensing process.

The Board contacted stakeholders comprised of its Rules Review Committee regarding the proposed rules. Committee members include individuals from hospital systems, specialty practices, academia, and retail settings. The Board also requested input from stakeholders operating as virtual wholesalers. From these distributions, it received feedback from virtual wholesalers regarding the requirement to obtain a Drug Enforcement Administration (DEA) license. This feedback indicated that DEA does not license these facilities because they do not possess controlled substances. The Board adjusted this requirement in the rule by instead requiring “a copy of any applicable federal licensure or registration.” No additional comments from early stakeholder outreach, nor from the CSI public comment period, were submitted indicating that the rules are overly burdensome. Therefore, the CSI Office has determined the purpose of the rules to be justified.

Recommendations

For the reasons discussed 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 Ohio State Board of Pharmacy 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