MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Christopher Smyke, Executive Assistant

DATE: November 29, 2016

RE: **CSI Review – Pharmacists & Dangerous Drugs (OAC 4729-9-09, 4729-27-01, 4729-9-17, 4729-5-10, 47-5-29, 4729-5-05, 4729-33-03, 4729-9-26, 4729-9-12, 4729-5-20, 4729-5-11, 4729-5-26)**

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 twelve rules submitted by the Ohio State Board of Pharmacy (Board) pertaining to the regulation of dangerous drugs and applicable healthcare professionals. There are two new and ten amended rules in this package. It was submitted to the CSI Office on September 28, 2016 and the comment period closed on October 12, 2016. Two comments were received during this time.

Of the two new rules, Ohio Administrative Code (OAC) 4729-9-09 permits a Pharmacy Board agent to make an on-site inspection of a location licensed as a wholesale or terminal distributor of dangerous drugs without notice. If the agent identifies a violation of Board rules or state or federal law, the rule requires a licensee to submit notification to the Board within 30 days to either correct or dispute the observed violation. The other new rule consolidates the Peritoneal Dialysis Solution Chapter (OAC 4729-27) into a single rule without any changes to the language. The ten amended rules make adjustments to the regulations for storage, disposal, Board notifications, recordkeeping, reporting, background checks, license validation and dispensing of

dangerous drugs. Two rules (OAC 4729-9-12 and 4729-5-26) are being proposed for amendment based on changes to federal law. The package also includes minor language and reference updates.

The BIA states that the impacted business community includes pharmacists/pharmacy interns, EMS agencies, dialysis solution distributors, terminal distributors of dangerous drugs, pain management clinics, prescribers and wholesale distributors of dangerous drugs. It indicates the nature of the impact to be the potential for discipline for pharmacists, interns, terminal and wholesale distributors that would result from violations of these rules. In addition, the BIA details the time and financial costs associated with maintaining compliance with each of the twelve rules. The Board justifies these rules, stating that the rules provide for patient safety and uniformity of care throughout Ohio. In addition, the BIA includes a detailed list of the specific functions that the Board is able to carry out as a result of these rules.

For stakeholder outreach, the rules were reviewed by the Board's Rules Review Committee, which is composed of pharmacists from many practice settings. This feedback led to four changes to the draft rules before they were submitted to CSI. The rules were also approved by the Board before filing with CSI. During the CSI review period, three comments were received.

Two of the comments related to proposed rule 4729-5-11, regarding an individual serving as a responsible person for a terminal or wholesale distributor of dangerous drugs. The Board addressed concerns that prohibitions against an individual serving as a responsible person were overly broad by changing the language to narrow the scope of violations that would prohibit responsible person status.

The third comment, from OhioHealth, expressed concern over the new Inspections and Corrective Actions rule (OAC 4729-9-09). Specifically, there was concern that the rule could be interpreted to mean that a Board agent could enter a pharmacy unannounced and unescorted, recommending that the language specify that agents present their credentials and reason for inspection. After considering this input, the Board amended the language to require agents to present their credentials upon inspection. In addition, the Board explained that while its agents are trained to provide a rationale for the inspection, a codified requirement to present a reason may complicate matters if the agent finds additional violations and the lack of an explanation becomes a liability in a court challenge.

After reviewing the proposed rule, the BIA, and the changes made by the Board in response to comments; the CSI Office has determined that the rule package satisfactorily meets the standards espoused by the CSI Office, and the purpose of the rule package is justified.

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 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