



MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Sydney King, Regulatory Policy Advocate

DATE: June 17, 2015

RE: **CSI Review – Controlled Substances (OAC 4729-11-01, 4729-11--02, 4729-11--03, 4729-11-04, 4729-11-05 and 4729-11-06)**

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 three amended¹ and three new rules. This rule package was submitted to the CSI Office on April 9, 2015, with the comment period ending April 24, 2015.

The rule package provides the controlled substance schedule category different pharmaceuticals will fall under. The requirements differ based on the schedule category. For example, more stringent requirements for a schedule I controlled substance may include increased security procedures, policies on the destruction of the controlled substance, and more detailed record-keeping policies. However, the draft rules only include the list of the pharmaceuticals under each category and not the requirements for utilizing the controlled substances. The Board communicated to the CSI Office that the rules are drafted in anticipation of legislative changes that will allow for more flexibility in responding to federal changes to the controlled substance

¹ Rules 4729-11-01, 4729-11--02, and 4729-11—03 are being amended by more than 50 percent. Therefore, the Legislative Service Commission requires that the existing rules be rescinded and replaced by new rules that have the same rule numbers.

schedule.

According to the BIA, the Board reached out to a representative group of stakeholders including several hospital systems and pharmacies. The BIA states that the feedback from the rule review committee was incorporated into the rule package. One comment was received during the CSI public comment period requesting flexibility for medical trials. The Board responded stating that flexibility is allowed with special permission from the Drug Enforcement Agency and the Board.

The Board identifies Ohio licensed pharmacists, terminal distributors of dangerous drugs and wholesale distributors 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, and that the rules are necessary to comply with federal controlled substance schedules.

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