MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: October 30, 2018

RE: **CSI Review – OARRS (OAC 4729:8-1-01, 4729:8-2-01, 4729:8-2-02, 4729:8-3-01, 4729:8-3-02, 4729:8-3-03, 4729:8-3-04, 4729:8-3-05, 4729:8-4-01, 4729:8-4-02 and 4729-37)**

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This rule package consists of twelve rescinded rules and ten new rules submitted by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on October 2, 2018 and the public comment period closed on October 16, 2018. No comments were received during this time.

The Chapter being rescinded governs the drug database for the Ohio Automated Rx Reporting System (OARRS). The new rules replace this Chapter, and provide definitions; the list of controlled substance drugs to be reported to OARRS; the list of non-controlled drugs of abuse to be reported to OARRS; the list of entities required to submit the sales of dangerous drugs to OARRS; the information that must be reported; the frequency and format for reporting; the process for correcting data errors in OARRS; and procedures for providing data and retaining information in OARRS. The proposed rules do not implement a federal requirement; the Board states that the operation of prescription drug monitoring programs has traditionally been done at the state level. ORC 4729.26, 3719.28, and 4729.84 give the Board authority to adopt rules

governing the distribution of dangerous drugs, prescribe recordkeeping standards, and establish and maintain a drug database such as OARRS.

As part of early stakeholder outreach, the Board distributed the rule package for initial public comment to entities on its stakeholder list. This included retail pharmacies, hospital pharmacies, prescribers, wholesalers, and manufacturers. The Board received feedback from OhioHealth and Pfizer. OhioHealth requested that the Board allow hospitals to report wholesale sales data to OARRS using an alternative method. The Board noted that the rules include an option for alternative reporting under a format that is mutually agreed upon by the Board and the hospital. Pfizer requested that the Board remove the requirement to report the purchaser's terminal distributor number as part of wholesaler sales data. The Board agreed to make this change. No comments were received during the CSI public comment period.

The rules impact pharmacies licensed as terminal distributors of dangerous drugs; wholesale distributors of dangerous drugs and manufacturers of dangerous drugs that sell controlled substances and other drugs of abuse in or into Ohio; prescribers who personally dispense controlled substances and other drugs of abuse from their offices; individuals seeking a copy of their own OARRS report; and, law enforcement. Entities required to submit the sales of dangerous drugs to OARRS will incur whatever administrative and technological costs are necessary to submit the data. This will vary greatly due to factors like size and scope of business, the Board notes that except for prescribers, this process is automated. Additionally, only a small amount of prescribers personally furnish reportable drugs so the costs of compliance will be minimized. Individuals seeking their own OARRS report will incur whatever cost is required to travel to the Board to request a copy of the report. Law enforcement professionals conducting investigations that require obtaining OARRS data are required to submit a formal request to access data in the system. The Board estimates that the form takes fifteen minutes to complete and submit.

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 standards for the information required to be reported to OARRS, as it is an integral part of tracking the dispensing and personal furnishing of drugs of abuse to patients. Monitoring this information helps to combat suspected abuse and diversion. Prescribers are also able to access critical information regarding a patient's prescription history, and identify high-risk patients who would benefit from early interventions.

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.