Common Sense Initiative

Mike DeWine, *Governor*
Jim Tressel, *Lt. Governor*
Joseph Baker, *Director*

MEMORANDUM

TO: Summer Reyburn, Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: March 28, 2025

RE: **CSI Review – Ohio Automated Rx Reporting System (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 4729:8-4-03)**

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 Board as provided for in ORC 107.54.

Analysis

This rule package consists of one new rule, seven amended rules, three no-change rules, and one rescinded rule proposed by the Ohio Board of Pharmacy (Board). This rule package was submitted to the CSI Office on November 4, 2024, and the public comment period was held open through December 13, 2024, after an extension from the original end date of December 2, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on November 4, 2024.

Ohio Administrative Code (OAC) 4729:8-1-01 contains definitions for terms that pertain to the Ohio Automated Rx Reporting System (OARRS). The rule is amended to add new terms related to central fill pharmacies, originating pharmacies, and medical marijuana dispensaries. OAC 4729:8-2-01 and 4729:8-2-02 list the drugs that must be reported to OARRS. The rules are proposed without changes.

OAC 4729:8-3-01 lists the entities that are required to submit information to OARRS with respect to dispensing, personal furnishing, or wholesale sales. The rule is amended to apply the requirement to licensed retail dispensaries and exempt opioid treatment programs (OTPs) from having to report patient data which is already reported via the Ohio Central Registry (OCR). OAC 4729:8-3-02 outlines the information that pharmacies, prescribers, drug distributors, and terminal distributors must submit to the Board. The rule is amended to include additional data fields that are part of the American Society for Automation in Pharmacy (ASAP) 5.0 data standard. OAC 4729:8-3-02.1, a new rule, was originally included as part of the rule package but was withdrawn by the Board before the end of the CSI public comment period.

OAC 4729:8-3-03 is rescinded and replaced by a new rule with the same number. The new rule sets forth the electronic format for transmitting required information to the Board about prescription dispensing and prescribers personally furnishing drugs. Compared to the rescinded version of the rule, the new version is revised to require all reporting to be conducted in accordance with the ASAP 5.0 data standard by July 1, 2026, and permit the Executive Director of the Board to grant extensions to the requirements of the rule. OAC 4729:8-3-04 establishes the frequencies by which terminal distributors, prescribers, and drug distributors must submit patient information to OARRS. The rule is amended to update grammar. OAC 4729:8-3-05 specifies how corrections should be made to data reported to OARRS. The rule is amened to update grammar and establish a process for making corrections to the drug database if a pharmacy utilizes a central fill pharmacy to dispense prescriptions. OAC 4729:8-4-01 sets forth the procedures by which those legally authorized to do so may obtain information from OARRS. The rule is amended to update grammar. OAC 4729:8-4-02 allows government entities and law enforcement agencies to request that specific OARRS data related to an open investigation be retained beyond the five-year retention requirement and authorizes the Board to provide database statistics and law enforcement outcomes under certain statutory conditions. The rule is proposed without changes. OAC 4729:8-4-03 permit certain persons to access OTP data provided by the Ohio Department of Mental Health and Addiction Services that is reported to OARRS. The rule is amended to update grammar and citations.

During early stakeholder outreach, the Board distributed the rules to stakeholders for public comment. The Board received comments expressing concern about the requirements to report specific data regarding secondary payment sources. As a result, the Board removed this provision from the rules. Commenters were also concerned about not knowing the species of an animal that is prescribed drugs, so the Board simplified the process for reporting the animal species code. During the CSI public comment period, the Board received eight total comments from individuals affiliated with Heart of Ohio Family Health (HOFH), Nationwide Children’s Hospital (NCH), the Ohio Council of Retail Merchants (OCRM), CenterWell Pharmacy, CVS Health, the Ohio Pharmacists Association (OPA), and the Cleveland Clinic.

NCH, the OPA, the Cleveland Clinic, and the HOFH commenters were worried about the possible negative effects of proposed new rule OAC 4729:8-3-02.1, which would have required pharmacies to obtain certain personal supplemental information from a patient. They argued that this would be a barrier to those seeking healthcare as this information could be sensitive for some patients, could lead to inconsistent responses at different locations, or may not be obtainable. The Board ultimately decided to withdraw the proposed new rule altogether while declaring its intention to revisit proposals to improve data matching and supplemental data at a later date. The OCRM and CVS Health requested clarification on the definition for "dispense" and believed that the rules did not account for the fact that some pharmacies have developed their own dispensing software. The Board clarified in rule that the date dispensed should be the date filled and revised the rules to allow pharmacies to indicate whether their dispensing software are their own proprietary systems. CenterWell Pharmacy, CVS Health, and the Cleveland Clinic believed that the collection of a pharmacist's national provider identifier and name if the pharmacist who conducts the drug utilization review is different from the dispensing pharmacist would be expensive, with CenterWell anticipating costs of at least $1 million to comply. After considering the difficulty and expense of collecting such information, the Board removed this requirement. The OCRM similarly believed that the transition to the ASAP 5.0 data standard would require the implementation of costly and time-intensive pharmacy system changes. After multiple discussions with CSI and the OCRM, the Board decided to extend the deadline to conduct reporting in accordance with the ASAP 5.0 data standard from December 1, 2025, to July 1, 2026, and remove the animal species code requirement, putting the rules more in alignment with similar regulations found in other states. Lastly, after conversing with CSI, the Board determined to remove the requirement for patients to have their form notarized when submitting a request to obtain their own OARRS database information.

The business community impacted by the rules includes pharmacies licensed as terminal distributors of dangerous drugs that dispense OARRS reportable drugs to patients in Ohio, distributors of dangerous drugs that ship OARRS reportable drugs into or within Ohio, prescribers who personally furnish controlled substances from their offices, and Ohio medical marijuana dispensaries. The adverse impacts created by the rules include the requirement to report drugs and relevant information to OARRS. The Board points out that the changes to the rules will result in additional administrative costs due to the need to capture more data in accordance with the ASAP 5.0 data standard, in addition to the increased information technology costs of updating computer systems to add more data fields for recording such data. Furthermore, the Board estimates that it takes ten to fifteen minutes to file an exception to the reporting requirements. According to the Board, the cost of obtaining an individual's OARRS report is free, but there are administrative costs associated with obtaining the report. The Board notes that OTPs are exempted from having to report to OARRS, as they already report the same information to the OCR. The Board states that the adverse impacts to business are justified to implement statutory requirements, protect and promote public safety, and collect data on drugs that are subject to abuse and diversion.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.