MEMORANDUM

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Travis Butchello, Regulatory Policy Advocate

DATE: June 16, 2017

RE: **CSI Review – Manner of Issuance; OARRS Reporting (OAC 4729-5-30, 4729-37-04, and 4729-37-05)**

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 three amended rules[1] proposed by the State of Ohio Board of Pharmacy. The rule package was submitted to the CSI Office on May 3, 2017 and the public comment period was held open through May 17, 2017. Seven comments were received during this time. Responses to the comments were provided to the CSI Office on May 28, 2017 and updated rules were provided on June 13, 2017 and June 16, 2017.

The amended rules provide changes to the Ohio Automated Rx Reporting System (OARRS), update language and terms, and add requirements involving reporting and dispensing information to the OARRS database. Specifically, Ohio Administrative Code (OAC) 4729-5-30 requires that all prescriptions contain a diagnosis code and number of days' supply on all controlled substances.

[1] Ohio Administrative Code (OAC) 4729-5-30 is being amended to the extent that the Legislative Service Commission requires the Board to rescind the rule and replace it with a new rule of the same rule number.

In addition, the rule specifies which portions of the prescription that a pharmacist may modify, and updates rule language requirements for generic substitutions, interchangeable biologics, and combined refills. The BIA states that the purpose of the rules is to implement new acute pain prescribing requirements to ensure patient safety, establish a thorough reporting mechanism to track controlled substances, and provide uniform regulations regarding the issuance of controlled substance prescriptions.

The Board explained in the BIA that it distributed the rules electronically for comment to entities representing Ohio prescribers and pharmacists as well as hospitals and chain pharmacies. The Board received extensive feedback from stakeholders. Eight comments were received regarding the days' supply provision. Commenters expressed concern that providers would be unclear of the Board's intent when using the term "intended days' supply" and if not included in the prescription, whether a pharmacist could contact a physician and add to the prescription. The Board responded with two amendments to the rule and decided to remove the word "intended" from the days' supply requirement and add a provision that a pharmacist may add days' supply after consultation with a prescriber or agent of a prescriber. Fifteen comments were received regarding Internal Classification of Disease (ICD) (for physicians) or Code of Dental Procedures and Nomenclature (CDT) (for dentists) coding. Commenters expressed concern that the description code was unnecessary and may be too confusing for some providers. In response, the Board decided to limit the ICD-10 coding to the first four characters to help eliminate any confusion for descriptive purposes.

In conjunction with the coding concerns, some commenters expressed discontent with the Board's requirement that prescribers with electronic prescribing systems comply with OARRS changes within ninety days. They argued that changes to their systems would be costly and likely require more time to implement. The Board responded and stated they would consider an extension to for compliance. Subsequently, the Board chose to adopt the change to extend the effective date to 120 days from the date of final filing and provided CSI with a revised copy of the draft rules on June 13, 2017.

During the early stakeholder outreach process, the Board also had extensive conversations with the Ohio Pharmacy Association (OPA). OPA took issue with pharmacy benefit managers not reimbursing prescribers if there was no ICD-10 code and wanted to ensure there were safety mechanisms in place in the rules to prevent such unintended repercussions. In response, the Board amended the rules and provided the updates to CSI on June 16, 2017, which allow prescribers to fill a prescription if a diagnosis code is missing and gives pharmacists authority to generate a code that specifies "no code provided" until the pharmacist is able to obtain the code from the prescriber. This will ensure that pharmacists are properly compensated and diagnosis codes are obtained to comply with reporting requirements for opioids.

Seven comments were received during the CSI public comment period and all of the commenters, including the Ohio State Medical Association (OSMA) and Ohio Hospital Association, expressed concern about the electronic prescribing system updates needed to comply with the diagnosis code requirement. The Board responded that if a prescriber cannot update their system, they can manually write the code on a prescription and fax it to the pharmacy instead. Emphasis was placed on the fact that the rules do not require a prescriber to use an electronic prescribing system and there are alternative methods to comply with the ICD-10 requirement without imposing an excessive burden on prescribers. OSMA reiterated their concerns about the ICD-10 code's effect on physicians. Specifically, they noted that the costs of compliance to upgrade electronic prescribing systems, time to look up the 4-digit diagnosis codes, and administrative costs, would have an immense impact on the practice of medicine and are not feasible. The Board acknowledges these costs, but justifies them because of the need to track opioid diagnoses to better understand and address the opioid crisis in Ohio while maintaining the highest standard of patient privacy. After further communications between CSI and OSMA, it was determined that there is a need for continued discussions with the Pharmacy Board and Medical Board particularly regarding the fiscal impact of the diagnosis code requirement. However, due to time constraints of this rule package, CSI recommends that the Board continue to engage stakeholders in further discussions while working through the Joint Committee on Agency Rule Review (JCARR) filing process.

The rules impact controlled substance prescribers, pharmacists, electronic prescription system vendors, and pharmacies across the state. Specifically, the adverse impact of the rules primarily exists in the context of updating prescribing systems. The BIA indicates that costs to update electronic prescribing systems will vary based upon the entity and the dispensing system vendor they use. In addition, the Board outlines in the BIA that there will be an administrative burden associated with the rules and will exist in the context of reporting, documenting, and inputting relevant diagnosis codes into the electronic system. The Board emphasizes that the purpose and intent of the rules justifies any adverse impact on business because the rules allow for the Board to protect and promote public safety to help improve the opioid epidemic.

Recommendation

For the reasons explained above, the CSI Office recommends that the Pharmacy Board continue to engage stakeholders and CSI in a discussion n the above issues as early as possible during the Joint Committee on Agency Rule Review process.

Conclusion

Based on the above comments, the CSI Office concludes that the Ohio Board of Pharmacy should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.