Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

MEMORANDUM

TO: Summer Corson, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: June 12, 2024

RE: **CSI Review – Continuous Quality Improvement and Duty to Report (OAC 4729:1-4-01, 4729:1-4-02, 4729:2-4-01, 4729:2-4-02, 4729:3-4-01, 4729:3-4-02, 4729:5-3-22, and 4729:5-4-02)**

On behalf of Lt. Governor Jon Husted, 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 Board as provided for in ORC 107.54.

Analysis

This rule package consists of five new rules, three amended rules, and three rescinded rules proposed by the State of Ohio Board of Pharmacy (Board) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on February 8, 2024, and the public comment period was held open through March 1, 2024. A supplemental public comment period was held from April 19, 2024, through May 13, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on February 8, 2024.

Ohio Administrative Code (OAC) 4729:1-4-01 authorizes the Board to take disciplinary actions against pharmacists or applicants for a pharmacy license for certain conduct. The rule is amended to update grammar and clarify that discipline will be carried out for errors in dispensing and product quality issues for compounded drug preparation only if they are the result of reckless behavior. OAC 4729:1-4-02 is rescinded and replaced by a new rule with the same number. The new rule requires pharmacists to report violations of Ohio laws and rules to the Board. OAC 4729:2-4-01 authorizes

the Board to take disciplinary actions against pharmacy interns or applicants for a pharmacy intern license for certain conduct. The rule is amended to clarify that discipline will be carried out for errors in dispensing and product quality issues for compounded drug preparation only if they are the result of reckless behavior. OAC 4729:2-4-02 is rescinded and replaced by a new rule with the same number. The new rule requires pharmacy interns to report violations of Ohio laws and rules to the Board.

OAC 4729:3-4-01 authorizes the Board to take disciplinary actions against pharmacy technician trainees, registered pharmacy technicians, certified pharmacy technicians, or applicants for such registration for certain conduct. The rule is amended to clarify that discipline will be carried out for errors in dispensing and product quality issues for compounded drug preparation only if they are the result of reckless behavior and allow the Board to prohibit an individual whose registration is suspended from being employed in a facility that is licensed by the Board to possess or distribute dangerous drugs. OAC 4729:3-4-02 is rescinded and replaced by a new rule with the same number. The new rule requires pharmacy trainees, registered pharmacy technicians, and certified pharmacy technicians to report violations of Ohio laws and rules to the Board. OAC 4729:5-3-22, a new rule, requires a pharmacy to establish or participate in a continuous quality improvement program to document and assess dispensing errors. OAC 4729:5-4-02, a new rule, requires a terminal distributor of dangerous drugs to report information to the Board concerning errors in dispensing and employees who have resigned or been terminated due to recklessness, unprofessional conduct, errors in dispensing, or physical or mental impairment related to substance use disorder.

During early stakeholder outreach, the Board issued the rules for public comment on two separate occasions. Stakeholders who were engaged included all licensees and pharmacy organizations such as the Ohio Pharmacists Association, the Ohio Hospital Association, and the Ohio Society of Health-System Pharmacy. Based on stakeholder feedback, the Board revised the rules to redefine what a prescription error is, permit third parties to conduct quality assurance reviews for dispensing errors, provide exceptions for contacting a patient who had a prescription error if the patient informed the pharmacy of the error, and limit disciplinary action to reckless behavior for pharmacy personnel who are responsible for an error in dispensing. During the initial CSI public comment period, the Board received comments from the Ohio State University Wexner Medical Center, the Ohio Society of Health-System Pharmacy, UC Health, CenterWell Pharmacy, Mount Carmel Health System (MCHS), University Hospitals (UH), Nationwide Children's Hospital, the Ohio Hospital Association, the Ohio Council of Retail Merchants (OCRM), and MetroHealth. During the supplemental comment period, the Board received comments from Fresh Encounter, Inc. (FE), Dayton Children's Hospital (DCH), the OCRM, UH, MCHS, and OhioHealth.

During the original public comment period, the commenters shared many of the same concerns about the potential impacts the proposed rules would have. The chief concern was the increase in reporting

requirements, particularly the expansion of the types of dispensing errors required to be reported to the Board. The commenters believed these new reporting requirements were excessive and would lead to a significant increase in the volume of reports to the Board. Furthermore, by mandating the reporting of dispensing errors that were not caused by reckless or unprofessional conduct, the commenters worried that many errors would go unreported and a lack of trust would develop among pharmacy staff. The commenters asserted that the new requirements would encroach upon the concept of Just Culture, which emphasizes that mistakes in pharmacy dispensing are typically a product of faulty organizational systems and cultures, rather than the person(s) directly involved, and which encourages the reporting of mistakes so that process can be reexamined internally to minimize future errors. There were also concerns about whether the Board could maintain the security of the additional reported information.

In response to the concerns raised by the commenters from the first comment period, the Board made several changes to the rules. The Board eliminated the required reporting for Category F errors that result in initial or prolonged hospitalization and cause temporary patient harm and reminded the commenters that only errors that are due to reckless behavior will result in discipline for the pharmacist, intern, or technician. Additionally, the Board deleted incorrect quantities and deliveries to wrong addresses as dispensing errors that needed to be reported. The Board also clarified that patient notification was only required if there is harm and provided more flexibility for pharmacies in occasions that warrant a root cause analysis. Other revisions the Board made to the rules in light of the comments included changing all record production requirements from immediate retrieval to three business days and only requiring the reporting of an individual with a drug or alcohol addiction if that individual engaged in the practice of pharmacy while physically or mentally impaired by alcohol or drugs. Some commenters considered certain rule provisions to be in conflict with Ohio's peer review statute in ORC 2305.25, but the Board replied that this section is applicable to civil actions related to a court of common pleas and does not mention administrative actions. A couple of commenters also believed that the definition of "dishonesty" was too broad and would consequently be problematic if required to be reported. The Board pointed out that dishonesty is statutorily listed as an offense for which it could take administrative action and was therefore important enough to be defined and reported.

During the supplemental public comment period, FE asked why a dispensing error would not include the delivery of an incorrect drug and whether errors reported to the Board were accessible to anyone. The Board replied that issues related to delivery were excluded from the definition of error in dispensing because it was working on a rule to address delivery services, adding that reported errors were shielded from disclosure under ORC 4729.23. UH expressed confusion over what would be required or would constitute a dispensing error regarding professional judgment and documentation. The Board revised the rules to clarify that review should be based upon policies and procedures and the development of an appropriate response, as opposed to a "one-size fits all" approach. DCH

recommended changing the requirement to submit a zero report from thirty days to monthly, while the OCRM asserted that this requirements was overly burdensome on a pharmacy team. MCHS advocated for the removal of this requirement entirely, which the Board ultimately determined to do. The OCRM also urged the Board to acknowledge the confidentiality protections of the Patient Safety Work Product when reporting safety events to a Patient Safety Organization pursuant to the federal Patient Safety Act. The Board referred to the language added to the rules that treats all reports as confidential under ORC 4729.23. MCHS and OhioHealth were concerned whether sensitive error information containing patient and employee data would be secured when it is reported to the Board after an error that could result in an unintended privacy issues. The Board modified the rules to limit the initial information provided to protect patient confidentiality, in addition to ensuring that all reports submitted are protected from disclosure under ORC 4729.23.

The business community impacted by the rules includes pharmacies licensed as terminal distributors of dangerous drugs, pharmacists, pharmacy interns, and pharmacy technicians. The adverse impacts created by the rules include the time and costs associated with developing a continuous quality improvement program, reporting information, and disciplinary actions for violations of Ohio laws and rules. Discipline may include reprimand, monetary fine, and/or denial, suspension, or revocation of a license. A monetary fine can be either $500 or $1,000, depending on the violation. Additionally, the Board estimates that it takes fifteen to thirty minutes to provide notification of violations. The Board pointed out that it removed the requirements for pharmacists, pharmacy interns, and pharmacy technicians to self-report voluntary treatment for mental health or substance use disorder. The Board states that the adverse impacts to business are justified to protect and promote public safety.

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.