Common Sense Initiative

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

MEMORANDUM

TO: Summer Reyburn, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: December 2, 2024

RE: **CSI Review – Outpatient Pharmacy Delivery Services (OAC 4729:5-5-26 and 4729:5-8-03)**

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 one new rule and one amended rule 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 August 19, 2024, and the public comment period was held open through September 13, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on August 19, 2024.

Ohio Administrative Code (OAC) 4729:5-5-26, a new rule, establishes standards for outpatient pharmacies with respect to medication delivery services to patients. The standards concern topics such as proper notification, temperature sensitive drugs, timeliness of delivery, compromised or lost drugs or devices, records, and contracts with third-parties. OAC 4279:5-8-03 contains various requirements for nonresident terminal distributors of dangerous drugs regarding topics such as records, labeling, compliance, disciplinary actions, prescriptions, supplying information to the Board, offering to counsel patients, inspections, reporting, and the sale or furnishing of controlled substances to Ohio patients. The rule is amended to require nonresident terminal distributors of dangerous drugs

to adhere to the delivery requirements of OAC 4729:5-5-26.

During early stakeholder outreach, the Board distributed the proposed rules to all Board licensees and registrants for public comment. As a result of the feedback received from this effort, the Board revised the rules to add a definition for "temperature sensitive drug," provide specific information on what must be provided to a patient who receives a drug via delivery, require pharmacies to take measures to ensure temperature integrity, clarify that the receiving party's signature may serve as proof of delivery, change the notification requirements for drugs experiencing a delay from twenty-four hours to forty-eight hours, remove common carriers from the contract requirements, and clarify that lost or stolen shipments should be reported in accordance with the Board's standard reporting rule. During the CSI public comment period, the Board received comments from Nationwide Children's Hospital (NCH), Cleveland Clinic, University Hospitals (UH), Hims & Hers (H&H), CenterWell Pharmacy (CenterWell), and an individual commenter.

NCH and H&H asked the Board to clarify who is considered a "common carrier." The Board added definitions for "common carrier" and "contract carrier" to ensure clarity. UH and NCH asserted that it could be challenging for pharmacies to notify patients within forty-eight hours of a delay. The Board stressed that it is important for patients to be informed of delays but altered the requirement to be within two business days to account for weekends and holidays. Cleveland Clinic and NCH asked the Board to clarify the duration for which records must be maintained in accordance with the rules. The Board added a provision requiring records to be maintained for three years. CenterWell and UH asked for clarification on what would qualify as a patient's general consent for delivery services, believing that requiring patient outreach prior to billing or delivery could lead to delays in therapy or prescriptions not being filled if a patient cannot be reached. The Board explained that consent is required prior to delivery but not prior to the shipment of each refill, noting that a pharmacy needs to contact a patient for billing information prior to shipping the drug regardless. However, the Board revised the rules to clarify how consent may be obtained. NCH, H&H, and the individual commenter expressed concerns about how replacement costs would be handled for compromised or lost drugs with respect to responsibility for bearing the costs, notice to the pharmacy, and the timing of a potential theft. The Board clarified in the rules that responsibility for replacement is borne by the delivery agent responsible for the loss, pharmacies must be notified by the patient before issuing a replacement, and the requirement only applies to drugs lost or stolen in transit. UH, Cleveland Clinic, and NCH urged the Board to clarify the level of information outpatient pharmacies must maintain about a pharmacy delivery agent. In response, the Board amended the rules to clarify what specific information is required based on the type of carrier utilized.

CenterWell believed that notifications to patients about their prescriptions should correspond to their communication preferences. The Board agreed and revised the rules accordingly. For consistency, as well as to avoid increased business expenses and increased pharmacy personnel time, H&H requested

that third-party entities only be required to participate in investigations if the loss of drugs and devices is significant. The Board incorporated this revision. H&H also suggested that only "known" theft be reported, but the Board replied that "known" is not a standard used in theft reporting. In addition, the Board answered questions asked for clarification by UH and the private individual concerning proof of receipt and by the individual commenter regarding the reporting of lost or stolen drugs. NCH and Cleveland Clinic urged the Board to provide more specific guidance regarding measures taken to properly maintain temperature-sensitive drugs. However, the Board replied that it was the pharmacy's responsibility to utilize best practices to maintain appropriate temperature levels to ensure the integrity of drugs. H&H and UH recommended that the requirement for an outpatient pharmacy to assist patients with arranging access to medication from a local pharmacy if such medication is not in stock only apply if feasible or be considered met if a good faith effort is made. The Board emphasized that the medications in question were life-sustaining, declaring that if a pharmacy takes on the responsibility of shipping a drug, then it must also accept the risk that a replacement must be provided. UH also argued that it would be an administrative burden on outpatient pharmacies and third-party delivery agents if they have to update existing contracts or make completely new agreements to ensure compliance with new recordkeeping requirements. The Board acknowledged UH's concerns but considered the requirement necessary to ensure that pharmacies have access to the required records in the event of a significant theft or loss, as this has been a problem in previous Board investigations.

The business community impacted by the rules includes terminal distributors of dangerous drugs that deliver medications to patients. The adverse impacts created by the rules include abiding by requirements related to medication delivery services and possible administrative licensure discipline for violation of the rules. Discipline may include reprimand, monetary fine, and/or suspension or revocation of a license. The new requirements will increase administrative costs, as pharmacies will need to modify their current delivery processes. Pharmacies will also be responsible for replacing any drug or device which is compromised or lost as part of the delivery process. The Board states that the adverse impacts to business are justified to protect and promote public safety, adding that more Ohioans are expected to rely on delivery services for medication access going forward.

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.