MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: August 20, 2018

RE: **CSI Review – Terminal Distributors (OAC 4729:5-1-01, 4729:5-2-01, 4729:5-2-03, 4729:5-2-04, 4729:5-3-04, 4729:5-3-07, 4729:5-3-08, 4729:5-3-09, 4729:5-3-10, 4729:5-4-01, and 4729-5-11)**

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This rule package consists of one rescinded rule and ten new rules submitted by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on February 8, 2018 and the public comment period closed on March 1, 2018. Two comments were received during this time. Responses to the comments were sent on April 23.

The rule being rescinded establishes the requirements for serving as a responsible person on a terminal distributor of dangerous drugs license. The proposed rules include this provision, while also detailing several other points: they provide definitions pertaining to terminal distributors of dangerous drugs; establish timelines for reporting a change in licensure status by a terminal distributor; detail procedures for discontinuing business, and transferring or disposing of drug stock; specify requirements for licensure verification by terminal distributors; provide standards for online pharmacies; set standards for the occasional wholesale sale of drugs by pharmacies; and establish the Board's authority to impose disciplinary actions on a terminal distributor of dangerous drugs.

The proposed rules do not implement a federal requirement; the Board states that the regulation of the pharmacy profession, oversight of the sale of prescription drugs, and the operation of pharmacies has traditionally been done at the state level. ORC 4729.26 gives the Board authority to adopt rules governing the distribution of dangerous drugs, to ensure that the practice of pharmacy and the dispensing of dangerous drugs are consistent throughout the state.

As part of early stakeholder outreach, the Board had the rules reviewed by its Rules Review Committee. The committee is composed of pharmacists from various practice settings, and it is responsible for reviewing and approving all rules. It expressed concerns about penalties for employing someone who had previously been disciplined, and asked for clarification on what entities the responsible person clause applies to. In response, the Board removed the provision on penalties, and specified that a responsible person can serve both a pharmacy and a hospital campus. The rule package as submitted to CSI reflects all stakeholder concerns raised during early outreach.

Two comments were received during the CSI public comment period. The Ohio Veterinary Medical Association (OVMA) expressed concern over the definition of "readily retrievable" in proposed rule 4729:5-1-01. The OVMA noted that the provision as written implies that veterinary clinics would have to keep a complete second set of records with only drug information, apart from the patient records. It suggested that the phrase "shall be kept in such a manner that they can be separated out from all other records" be deleted to eliminate any ambiguity. The Board amended the rule to accommodate OVMA's request. Two other concerns noted by the OVMA dealt with rule 4729:5-3-08 which details requirements for online sales, and 4729:5-2-01 which covers "inappropriate prescribing."

With respect to online sales, the OVMA felt that the provision stipulating that a licensee "offering to sell" dangerous drugs must obtain accreditation as a verified internet pharmacy was unnecessarily duplicative, and costly for veterinary clinics. It stated that in a scenario where multiple clinics use the same purveyor for online sales each clinic would have to register and pay costs for accreditation because they "offer to sell." OVMA suggested that there be an exception for license holders "offering to sell" in concert with an online pharmacy which itself has accreditation as a verified internet pharmacy. The Board amended the rule to accommodate the request.

The OVMA's final comment dealt with the effects of the "inappropriate prescribing" provision in proposed rule 4729:5-2-01. It expressed concerns that veterinarians who are disciplined by the Veterinary Licensing Board for prescribing the wrong drug, which has nothing to do with opioids or diversion, could also be disciplined by the Pharmacy Board under this provision, rendering them unable to obtain a terminal distributor license. The Board explained that the provision

contains the same language as the previous responsible person rule, and that all licensing decisions are made on a case-by-case basis with all necessary context taken into account. The Board felt that the scenario proposed by OVMA is highly unlikely to occur, and declined to amend the rule.

Hospice provider LeadingAge made two comments concerning the proposed rules. It expressed concerns that its usual practice of waiving copays could be seen as "enticement" under rule 4729:5-4-01, and that the shortage of physicians with advanced certification in hospice and palliative care would prevent many providers from meeting certification requirements under 4729:5-2-01. The Board noted that neither of these provisions would have an effect on hospice providers, so the rules did not need to be amended.

The rules impact all terminal distributors of dangerous drugs and their employees. All terminal distributors that sell dangerous drugs at retail in the state of Ohio must obtain a license. Any person selling dangerous drugs online at retail into or out of Ohio must also obtain licensure as a terminal distributor. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually, and the license application takes between 30-60 minutes to complete. Once a license is issued, a terminal distributor must complete an annual inventory of all controlled substances, which the Board estimates takes several hours to complete. Online sellers must also obtain accreditation from the National Association of Boards of Pharmacy. The application fee for accreditation ranges from $5,000 to $8,000.

Violations of the rules may result in administrative licensure discipline. This includes reprimand, denial of a license, suspension of a license, monetary fines, and revocation of a license. 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 the legitimacy of online pharmacies, deter and detect diversion of controlled substances, and prevent illegal sales of dangerous drugs.

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.