MEMORANDUM

TO: Cameron McNamee, Ohio State Board of Pharmacy

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: August 9, 2018

RE: **CSI Review – Drug Distributors (OAC 4729:6-1-01, 4729:6-2-01, 4729:6-2-02, 4729:6-2-03, 4729:6-2-04, 4729:6-2-05, 4729:6-2-06, 4729:6-3-04, 4729:6-3-05, 4729:6-3-06, 4729:6-3-07, 4729:6-3-08, 4729:6-4-01, 4729:6-5-01, 4729:6-5-02, 4729:6-6-01, 4729:6-7-01, 4729:6-8-01, 4729:6-8-02, 4729:6-9-01, 4729:6-9-02, 4729:6-10-01, 4729:6-10-02, 4729:6-11-01, 4729:6-11-02, 4729-9-07, 4729-9-08, 4729-9-12, 4729-9-13, 4729-9-16, 4729-9-18, 4729-9-19, 4729-9-24, 4729-9-27, 4729-9-28, 4729-9-29, 4729-9-30, and 4729-16-02)**

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This rule package consists of thirteen rescinded rules and twenty-five new rules submitted by the State of Ohio Board of Pharmacy (Board). The rule package was submitted to the CSI Office on March 6, 2018 and the public comment period closed on March 21, 2018. Seven different groups submitted comments during this time and multiple stakeholder meetings have been held since the comment period closed.

In an effort to combat the opioid epidemic in Ohio, the Pharmacy Board is promulgating rules that will regulate the operation of drug distributors. Eleven of the thirteen rules being rescinded are being replaced by one of the proposed rules. Ohio Administrative Code (OAC) 4729-9-18 and 4729-9-27 are being rescinded with no replacement. These rules require a drug distributor's

Board license to be maintained onsite in a readily retrievable location, and require compliance with the Drug Enforcement Agency (DEA) regulations regarding employment of individuals with felony convictions.

The proposed rules regulate the licensure of drug distributors, security of controlled substances, recordkeeping, reporting of suspicious orders to the Pharmacy Board, verification of licensure prior to the sale or purchase of controlled substances, and background checks for owners and responsible persons. The proposed rules do not implement a federal requirement; the Board states that the regulation of dangerous drugs 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 dispensing of dangerous drugs is consistent throughout the state. The Board notes that some of the proposed rules exceed provisions specified by the federal government, but that stricter regulations were necessary in some contexts to ensure public health and safety, and to prevent diversion of controlled substances.

As part of early stakeholder outreach, the Board distributed the rule package to all Ohio licensed drug distributors for initial public comment. The Board received feedback from ten different entities regarding license application timelines, procedures involved for cessation of operations, license verification requirements, transportation and storage requirements, suspicious order reporting, and other general clarification requests. Based on stakeholder feedback, the Board made clarifications and incorporated several changes: the Board clarified that only facilities in Ohio or facilities used to ship drugs into Ohio must be indicated on a license application; changed language in OAC 4729:6-2-05 to require new applications within thirty days of a change in business description, rather than prior to a change; specified the circumstances where the executive director or designee may waive the requirement to file a discontinuation of business form with the Board before ceasing operations; modified the license verification provision to require the purchasing drug distributor to verify a seller's license annually; clarified that website requirements only apply to drug distributors who sell or offer to sell dangerous drugs online; modified transportation and storage provisions to require adherence to federal requirements; and created a new requirement related to reporting customers, and potential customers, who may be engaged in drug diversion.

Numerous comments were received during the CSI public comment period from seven different groups. Most of the concerns raised prompted the Board to make additional clarifications and, in some cases, modifications to the rules. The Board removed provisions requiring drug distributors to provide information on licensing exemptions to prescribers, and expanded the provision requiring license verification so that using the Board's online roster is not mandatory. It also removed the due diligence provision from a rule based on concerns that annual onsite visits are not necessary for all customers. The Board also made a number of minor clarifications to the rules, in order to resolve ambiguities, and confusion about their application. These clarifications

touched on a variety of subjects including orders for controlled substances; reporting requirements for out-of-state customers; orders from other drug distributors; emergency orders; customer lists; and recordkeeping for wholesale distributors.

After the Board's initial response to public comments, Pfizer and Amerisource Bergen raised additional concerns about a number of provisions. CSI conducted stakeholder meetings with both groups, individually, to address these outstanding issues. Pfizer noted concerns with the criminal records check, and suspicious order monitoring provisions in its stakeholder meeting. It noted that as an international company it would be burdensome to have a large number of senior-level executives subject to a criminal records check. It suggested requiring only employees with direct authority over drug distributing activities to be subject to the provision, and asked the Board to consider treating large entities differently under this provision. With regard to suspicious order monitoring, Pfizer asked for clarification about what constitutes a suspicious order, and whether it would only apply to Ohio customers. The Board clarified in the stakeholder meeting that it is only interested in Ohio customers for the purpose of the rules.

Pfizer also noted that reporting suspicious orders as they occur would cause significant administrative costs, and seems redundant given that they are already required to provide the Board with a distribution sales report. The Board explained that distributors will be able to time reports so that they coincide with distribution sales and other reports. Moreover, it noted that the report should not cause a significant administrative burden because the process that will be used consists of a distributor selecting "yes" or "no" to indicate whether it had any suspicious orders that month. In addition to its concerns about suspicious order monitoring, Pfizer also took issue with the responsible person provisions. It stated that conducting a full inventory would require a complete shut-down of a facility during that time, and to do this each time a new responsible person was designated would be quite burdensome.

The Board agreed to make additional amendments following the stakeholder meeting with Pfizer. With regard to the criminal records check, the Board incorporated new language that would allow it to consider a distributor's corporate structure to determine who should be subject to criminal records checks. It also added language to allow corporations to request a waiver for criminal records checks under certain circumstances. The Board also amended the responsible person provision to address Pfizer's concerns over having to do a full inventory immediately upon designating a new responsible person. It stressed in its response that it was important to maintain the requirement because the responsible person must be made aware of the operations, and their potential personal liability in the event of noncompliance. It did increase the timeframe under which the inventory must be conducted, extending it to thirty days from the separation date of the previous responsible person.

Amerisource Bergen also noted outstanding concerns regarding the proposed criminal records

check, and suspicious order monitoring provisions. It stated that the criminal records check provision as written would be problematic due to Amerisource Bergen's size. Many of its executive employees with the title of President or Vice President would be subject to a criminal records check, even when they have no direct involvement with the activities addressed by the rules. With regard to the suspicious order monitoring provisions, Amerisource Bergen stated that the rule would require them to completely change their current procedures for flagging and reporting suspicious orders. It asserted that compliance with the Board's proposed requirements would cause them to incur an extreme administrative burden beyond their available resources. It noted that due to the volume of customers the company serves it would be impractical for it to distribute and review annual questionnaires, and develop separate procedures for its in-state and out-of-state customers.

In its response to these concerns, the Board declined to make changes. It noted that the suspicious order monitoring requirements are based on recommendations issued by the DEA, and that the goal of preventing diversion merits the provision. It also stated that it would be open to discuss timeframes for customer data collection, but does not intend to relax the due diligence requirements further than that. With regard to the criminal background check, the Board noted its amendments following the Pfizer stakeholder meeting. It stated that those amendments also address Amerisource Bergen's concerns about the provision.

The rules impact all drug distributors licensed in the state of Ohio. This includes wholesalers, manufacturers, third-party logistics providers, outsourcing facilities, and repackagers. Licensure as a drug distributor costs between $1,900 and $2,000 biennially, and the license application takes between one and two hours to complete. Certain individuals employed by the distributor will have to undergo a criminal records check, at a cost of $46. Distributors must submit a new application if there is a change in ownership, business name, category, or address, and pay the license fee. Virtual wholesalers or third-party logistics providers who are not licensed in their home state must obtain and maintain Verified-Accredited Wholesale Distributors accreditation from the National Association of Boards of Pharmacy. The accreditation is $5,500 in the first year and then $7,500 every three years thereafter.

Once a license is issued, the distributor will have to abide by the requirements in the proposed rules. Distributors must verify licensure prior to the sale or purchase of dangerous drugs; report suspicious orders and customers to the Board; abide by federal guidelines for controlled substance inventory procedures; and maintain records pertaining to the sale and distribution of complimentary drugs and samples. Costs associated with these provisions stem from the administrative costs required to comply, such as compensation for additional employee time spent recording and maintaining the required information.

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. The costs are justified as Ohio faces an unprecedented opiate epidemic and the Board is taking steps to aid in the fight against this epidemic. It emphasizes that the rules serve to ensure uniform regulations to protect the health and safety of Ohioans by providing standards for the security and control of dangerous drugs, and identifying and reporting possible drug diversion.

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.