MEMORANDUM

TO: Erin Reed, State of Ohio Board of Pharmacy, Medical Marijuana Control Program

FROM: Emily Kaylor, Director of Regulatory Policy

DATE: June 8, 2017

RE: **CSI Review – Medical Marijuana Control Program: Dispensary Rules (OAC 3796:6-1-01, 3796:6-2-01 to 3796:6-2-14, 3796:6-3-01 to 3796:6-3-24, 3796:6-4-01 to 3796:6-4-10, and 3796:6-5-01)**

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 50 new rules proposed by the State of Ohio Board of Pharmacy. The rule package was submitted to the CSI Office on March 9, 2017, and the comment period remained open until March 24, 2017. The Board submitted a revised BIA on May 3 to add clarity to a few responses and to provide more detail on the rules' adverse impacts on regulated entities. Final revisions to the rules were submitted on May 23 with one clarifying amendment submitted on June 1.

The proposed rules, which are statutorily mandated in recently-enacted ORC Chapter 3796, make up the second of multiple rule packages that cover responsibilities divided among three agencies under Ohio's Medical Marijuana Control Program. Of these three agencies—including the Ohio Department of Commerce, the State of Ohio Board of Pharmacy, and the State Medical Board of Ohio—the State of Ohio Board of Pharmacy is responsible for the administration, implementation, and enforcement of rules pertaining to dispensaries, patients and caregivers, and the forms and methods of administration for medical marijuana. The rules in this package deal with dispensaries, defined as those who are licensed to sell medical marijuana to qualifying patients and caregivers. The proposed rules cover topics including, but not limited to, definitions, provisional licenses and certificates of operation, inspections, change in ownership, hours of operation, designated representatives, security, dispensing, labeling, reporting, employee training, recalls, advertising, fees,

and prohibited activities.

As dispensaries will be the sole entities authorized to sell and dispense medical marijuana to patients and caregivers in Ohio, entities that are issued applicable certificates of operation will be impacted by the proposed rules. Potential adverse impacts of the rules include paying application, licensing, and renewal fees; reviewing policies and procedures at least annually; maintaining evidence of financial responsibility via an escrow or surety account, or a surety bond; compiling required information for creating operations, security, and financial plans; completing an application; preparing and filing reports; recordkeeping and record storage; notifying the Board and requesting an inspection; providing patients with adequate educational materials; training employees (employees are also required to obtain sixteen hours of continuing education every two years); and covering various other costs, such as paying for background checks, performing proper waste removal, and meeting security requirements. Finally, violations of the rules or ORC Chapter 3796 could result in fines of up to $50,000 per violation, or could lead to the revocation, suspension, or termination of a medical marijuana dispensary certificate of operation or employee license.

The BIA prepared by the Board states that the rules are justified because they are required by statute and provide a balanced, transparent, and accountable method for allowing individuals and entities to obtain and maintain dispensary licenses. The rules also ensure that patients receive a safe and consistent product, and afford patients and caregivers a safe and secure location from which to purchase medical marijuana. Finally, the rules promote safe and temperate use of medical marijuana, while reducing risks associated with the diversion and theft of medical marijuana. Beginning September 9, 2018, the Board provides flexibility in the rule to allow for the issuance of additional dispensary licenses if, based on population, patient demand, and the geographic distribution of dispensary sites, an increase would help ensure patient access to medical marijuana.

Beginning in December 2016, the Board engaged Ohio citizens, businesses, advocacy groups, prospective patients and caregivers, industry associations, and the Medical Marijuana Advisory Committee in discussions regarding the proposed rules. It also conducted a survey of persons eligible to serve in the position of clinical director. As a result of these discussions, the Board received more than 300 early stakeholder outreach comments, the majority of which fit into seven categories: advertising, number of dispensary licenses, fees, the prohibition on home delivery of medical marijuana, purchasing options, dispensary hours of operation, and the requirement that each dispensary employ a part-time clinical director. After reviewing each comment, consulting with industry experts, and speaking with stakeholders, the Board made several revisions to the rules before submitting them for review by the CSI Office.

These revisions include lifting pre-approval requirements on advertising and replacing them with a requirement to submit advertisements prior to publication; adding prohibitions on the following items, based on requests made by most stakeholders commenting on advertising: slang terms, broadcast ads, clothing, handheld signs, and marijuana leaves; increasing the initial number of dispensary provisional licenses available for issuance before September 8, 2018 from 40 to 60; decreasing the biennial fee for a dispensary certificate of operation from $80,000 to $70,000;

clarifying that the Board will return collected fees to applicants if a request for application is withdrawn before awards are made, or if the Board grants permission for application withdrawal due to a federal, state, or local change in rules or regulations; adding a prohibition, per the suggestion of Committee members, on dispensaries being located within 500 feet of a rehabilitation facility; removing the requirement for a clinical director, while also enhancing training-focused rules to require contracting with certain professionals to develop training content; expanding permitted hours of operation by two hours; adding whistleblower protections to protect employees; revising the rules to allow dispensaries to sell expired plant material to a licensed processor, enabling dispensaries to profit off of what would otherwise be rendered useless; including a provision to allow dispensaries to accept unused medical marijuana from patients and caregivers for destruction; and modifying security and surveillance requirements to allow for live streaming from a motion-activated camera, rather than a 24-hour recording, during hours when a dispensary is closed. Due to early public feedback, the prohibition on home delivery remains in the rules, as does a prohibition on coupons and discounts for anyone who is not a veteran or indigent.

During the CSI public review period, interested parties submitted nine comments. While the comments did not reveal any noticeable themes, two mentioned a concern with the proposed fee structure. To justify the required fee of $70,000 for a dispensary certificate of operation, the Board explained that the fees are purely based on administrative costs, meaning they will be used to fund things like personnel (including those working on compliance and licensing), training, the E-licensing system, travel costs, the patient registry identification system, and the toll free line. The Board also noted that the Medical Marijuana Control Program is completely self-funded, not funded by tax dollars, and that licensing fees (on a biennial basis) remain in line with many other states that have legalized medical marijuana. Finally, the fee structure could be amended in the future if the Board determines that it has overestimated projected costs for program implementation.

Besides fees, other comments submitted by stakeholders expressed concern about needing to know where district boundaries will lie; the difficulty of integrating scanning hardware for the patient registry identification system with the statewide inventory tracking system; needing to allow for containers that hold smaller amounts of medical marijuana products than what is originally prepared; and labeling requirements, specifically that labels should include a product's method of administration. In response to these concerns, the Board confirmed that it has gathered extensive data to put towards determining dispensary districts, and that the geographic distribution will be revealed as soon as it is finalized. The Board has received population data and is working to ensure access to dispensaries will be distributed across the state. Regarding the difficulties of electronic integration, the Board committed to providing dispensaries with the first round of scanners for scanning patient identification cards, and that these scanners will be programmed to integrate seamlessly. Moreover, additional scanners can be purchased from a designated vendor, or that vendor can program the registry to recognize the scanner, if appropriate. The Board also revised the appropriate rule to authorize dispensaries to provide a container intended to hold smaller quantities of medical marijuana, a revision that was also reflected in the Patient and Caregiver rules. Finally, the Board acknowledged that the method of administration should indeed be added to the labeled product sold in the dispensary. After conversations between the Board and the Department of Commerce, it was

determined that this was best suited to be included in the Department of Commerce's processor rules, not part of this package.

Other stakeholders offered recommendations that the Board chose not to adopt, and justified its reasons. However, there was concern from the Ohio Insurance Institute regarding the availability of a bond, escrow account, or surety account in the marketplace. In response, the Board amended the rules to provide an exemption should the provisions not be available.

After reviewing proposed revisions to the rules, the CSI Office engaged in conversations with the Board to discuss outstanding concerns it felt needed to be addressed. As a result of those conversations, amended rules along with an updated BIA and responses to questions were provided to CSI on May 3. Some of these changes included clarifying time periods that were vague in the rules, correcting grammatical errors, and ensuring that language was consistent. One additional change was made to clarify that an individual applying for an initial associated key employee license would only have to pay the required fee upon award of a provisional license, and this updated rule was provided to CSI on June 1.

Throughout the rule drafting and review process, the Board engaged in significant outreach and conducted a rulemaking process that was both transparent and accessible to industry experts and potential business stakeholders. This is especially apparent in the significant decrease in the number of comments received between early stakeholder outreach and the CSI public comment period. In light of this and the aforementioned revisions to the rules, the CSI Office has determined the purpose of these rules to be justified.

Recommendations

For the reasons discussed above, the CSI Office does not have any recommendations for this rule package.

Conclusion

Based on the preceding comments, the CSI Office concludes that the State of Ohio Board of Pharmacy, Medical Marijuana Control Program should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.