



## Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Carrie Kuruc**, Director

### MEMORANDUM

**TO:** Alexandra Simon, State of Ohio Board of Pharmacy

**FROM:** Ethan Wittkorn, Regulatory Policy Advocate

**DATE:** June 3, 2021

**RE:** CSI Review – Dispensary Operations (OAC 3796:6-3-01, 3796:6-3-02, 3796:6-3-03, 3796:6-3-05, 3796:6-3-06, 3796:6-3-08, 3796:6-3-11, 3796:6-3-12, 3796:6-3-13, 3796:6-3-14, 3796:6-3-15, 3796:6-3-16, 3796:6-3-17, 3796:6-3-18, 3796:6-3-19, 3796:6-3-20, 3796:6-3-21, 3796:6-3-22, and 3796:6-3-23)

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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This State of Ohio Board of Pharmacy (Board) rule package consists of two new rules, 17 amended rules, and two rescinded rules. It was submitted to the CSI Office on July 13, 2020, and the public comment period was open through August 3, 2020. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on July 13, 2020.

The rules proposed establish standards for the operation of medical marijuana dispensaries, including requirements for reporting and record keeping, packaging and labeling, employee training and identification, hours of operation, designated representatives, receipts, dispensing of medical marijuana, quality assurance and recalls, methods of disposal, educational materials, security, inventory systems, and prohibitions for dispensaries. Two new rules are proposed to replace rescinded rules that require dispensaries to monitor for any theft or loss of medical marijuana and report any such incidents to the Board and require dispensaries to ensure the confidentiality of all patient transaction records. Amendments being proposed to the rules include updates to when

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packaging can be modified, prohibiting dispensaries from being within 500 feet of an opioid treatment center, requiring dispensaries to establish and maintain written procedures for operations, requiring the display of a placard where edible products are sold, including hours of operation on a dispensary website, and requiring dispensary hour changes to be approved by the Board. Further amendments mandate that employee cards be destroyed after a key employee separation, add that patients be communicated with as part of quality assurance plans, require that dispensing errors be reported to the Board within 24 hours, update methods of destruction and the return of recalled products, remove the effectiveness of various marijuana strains from patient educational material, and add a duty to report to employee training. Lastly, amendments require recalled products be returned to the licensed cultivator or processor, that no food or beverages be offered on premise, and to make general language updates.

During the period of early stakeholder outreach, the Board submitted the proposed rules to the Medical Marijuana Advisory Committee, and the Board's staff obtained approval from its members prior to filing the rules with CSI. During this time, the Board considered stakeholder comments that were submitted during the development of the rules. During the CSI public comment period, 23 comments were received. Comments led to updates that include the removal of language in OAC 3796:6-3-01 to avoid confusion, reducing the waiting period for hours of operation updates to 30 days, extending the reporting deadline for dispensing errors to 48 hours, adjusting audit rules to remove requirements for a licensed independent auditor, and allowing for patients or caregivers to be accompanied by an adult individual in a waiting area.

Following the CSI public comment period, additional comments were submitted by representatives of Green Thumb Industries (GTI) expressing outstanding concerns regarding the audit process. GTI stated that, as a publicly-traded entity, they are already required to file an extensive financial report with the Canadian Stock Exchange and the U.S. Securities and Exchange Commission (SEC), which they believe makes the requirements in OAC 3796:6-3-20 duplicative and costly for them and other publicly-traded companies. Therefore, GTI suggested that a dispensary be able to file a profit and loss statement for licensed facilities and a balance sheet of the legal entity holding the dispensary license, prepared under generally accepted accounting principle standards, if the dispensary is owned by a publicly-traded company that files a quarterly 10Q with the SEC. Additionally, GTI suggested the addition of language that, following the end of a fiscal year, a dispensary owned by a public company may submit the company's 10K as-filed with the SEC as long as it is audited by an independent auditor or certified public accountant, in lieu of current requirements. After receiving the stakeholder's comments, CSI urged the Board to re-engage with stakeholders to discuss these concerns. As a result of continued discussions, the Board made further amendments to the rule to allow operators to file consolidated audits, identifying in the documents where the Board can find the required information. Additionally, the Board made changes to allow audits to be approved by

an operator's chief financial officer and to require audits at the end of the fiscal year rather than quarterly.

Impacted communities include medical marijuana dispensaries and dispensary employees. Adverse impacts include potential administrative discipline for violation of the rules. This discipline may manifest in the form of reprimand, denial of licensure, license suspension, license revocation, and fines. Additional impacts identified by the Board include administrative costs to comply with record keeping and reporting requirements, costs to provide modified containers when necessary, maintaining premise requirements including signage and distance from prohibited facilities, administrative costs to destroy separated employee identification cards, costs to establish quality assurance and recall provisions, establishing security protocols, complying with employee training requirements, complying with prohibitions for dispensaries, and maintaining restricted access areas. The Board states that the rules are necessary to protect the health and safety of those participating in Ohio's medical marijuana program.

### **Recommendations**

Based on the information above, the CSI Office has no recommendations on this rule package.

### **Conclusion**

The CSI Office concludes that the Board proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.