



MEMORANDUM

TO: Justin Hunt, Ohio Department of Commerce, Medical Marijuana Control Program

FROM: Emily Kaylor, Director of Regulatory Policy

DATE: June 9, 2017

RE: **CSI Review – Medical Marijuana Control Program: Testing Lab Rules (OAC 3796:4-1-01 through 3796:4-1-09, 3796:4-2-01 through 3796:4-2-09, and 3796:4-3-01)**

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 nineteen new rules proposed by the Ohio Department of Commerce. The rule package was submitted to the CSI Office on May 4, 2017, and the comment period remained open until May 19, 2017. Changes were made to the rules and the final versions were submitted to CSI on June 8.

The proposed rules, which are statutorily mandated in recently-enacted ORC Chapter 3796, make up one of multiple rule packages that cover responsibilities divided among three agencies under Ohio's Medical Marijuana Control Program. The rules in this package stipulate the application and operation requirements for labs that will test medical marijuana products in Ohio before they can be sold. In addition to testing medical marijuana products from processors, testing labs will also collect samples of harvested plant material from cultivators to ensure proper fertilizers and pesticides are being used. The proposed rules cover topics including the application submission and review processes, facility sanitation requirements, guidance on what to test for, disposal of lab waste, security standards, inspections, and recordkeeping. Fees for testing lab applications and renewals were established in Ohio Administrative Code 3796:5-1-01, not part of this package. There are no limits on the number of testing labs in Ohio.

The Department received early comments on the rules from citizens, businesses, advocacy groups, and industry associations. Three comments expressed concern that higher education institutions would not be interested in serving as testing labs, which is a legislative requirement for the first year of operation. The other comment wanted stricter requirements for microbiological testing but the Department felt the rules were specific enough to ensure patient safety while broad enough to allow for lab flexibility. The Department made some changes to the rules at the request of industry stakeholders to clarify language.

During the CSI public review period, three comments were received. All of the comments raised concerns regarding the higher education institution requirement. Some are worried this will delay testing as institutions choose not to apply and the state is left without qualified testing labs in the first year of the program. Aware of this concern and knowing it was a requirement of House Bill 523 of the 131st General Assembly, the Department is actively seeking solutions to ensure testing is operational by September 2018 so that Ohioans have access to safe medical marijuana products. A comment was received that raised concerns over restricting an individual associated with a testing lab from having an ownership or investment interest in any other medical marijuana entity. However, the Department insists on this requirement to ensure that testing of medical marijuana is fair, independent, and not influenced by one's financial interests in the product. This comment also requested that labs have more freedom to perform research and make claims regarding the benefits and harms of medical marijuana, but the Department regulates these labs as quality assurance entities, not research labs.

These rules will impact medical marijuana testing labs. As stated above, fees are set for testing labs in another rule but will be \$2,000 for applications, \$18,000 if the applicant is awarded a certificate of operation, and \$20,000 for annual renewal. The BIA explains that many of the costs associated with this industry are unknown, but the Department expects testing labs to incur costs associated with employee training and registration, security requirements, disposal of material after analysis, financial responsibilities, and reporting requirements. The Department justifies these costs as the rules are necessary to establish this unique industry in Ohio and ensure that medical marijuana products are accurately tested before sale to protect the health of medical marijuana patients.

The Department engaged in significant outreach and conducted a rulemaking process that was both transparent and accessible to industry experts and potential business stakeholders. In light of this, the aforementioned revisions to the rules, and further clarifications from the Department, 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 Ohio Department of Commerce should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.