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: Processor Rules (OAC 3796:3-1-01 through 3796:3-1-10, 3796:3-2-01 through 3796:3-2-08, and 3796:3-3-01)**

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 April 7, 2017, and the comment period remained open until April 21, 2017. The Department provided updated rules on May 25 and further changes were made 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 set the application and operation requirements for the up to 40 processor licensees the Department will regulate. The proposed rules cover topics including the number of licenses, application submission and review, financial responsibilities, changes in ownership or location of the processor, an uninterrupted supply standard, proper disposal of medical marijuana waste, packaging and labeling requirements, recordkeeping and reporting, and other quality assurance standards. Fees for processor applications and renewals were established in Ohio Administrative Code 3796:5-1-01, not part of this package.

The Department received early comments on the rules from Ohio citizens, businesses, advocacy groups, and industry associations. Nineteen comments were received regarding security system requirements, fees and financial barriers, increasing the number of licenses, limiting solventless

extracts, and some requests for an Ohio residency requirement. Based on this feedback, the Department expanded language regarding non-solvent extraction methods, ensured their package and label requirements were consistent with the Pharmacy Board's rules, allowed security systems to have motion sensor recording instead of 24-hour coverage, reduced the surety bond and escrow amounts, added a provision to allow processors to acquire expired plant material from dispensaries, and removed designated geographic territories. The Department did not add an Ohio residency requirement but states in the rules that it may consider whether an applicant is an Ohio business with persons associated with it as residents of Ohio. It also kept the initial number of licenses at 40 which will be re-evaluated after the first year of operation.

During the CSI public review period, three comments were received. One provided suggestions to increase security standards in all of the medical marijuana rules, but the Department felt they would be overly burdensome and the processors should have some flexibility in their facility. The other two provided specific comments on rule language to which the Department either explained its choices to CSI or made rule changes. For example, the Department initially required applicants to demonstrate their compliance with all building, fire, safety, and zoning statutes. However, an applicant who is in the process of building or has not started to build a facility could not provide this documentation. The Department clarified the language so that applicants have to provide documentation that they are currently in compliance or will be in compliance prior to receiving a certificate of operation if selected.

These rules will impact processors of medical marijuana. As stated above, fees are set for processors in another rule but will be $10,000 for applications, $90,000 if the applicant is awarded a certificate of operation, and $100,000 for annual renewal. The BIA explains that many of the costs associated with this industry are unknown, but the Department expects processors to incur costs associated with packaging and labeling, transporting the material, required recordkeeping and reporting, lab testing of material, and waste removal. The Department justifies these costs as the rules are necessary to set-up this unique industry in Ohio and ensure safe manufacturing of medical marijuana products.

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.