



MEMORANDUM

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

FROM: Emily Kaylor, Director of Regulatory Policy

DATE: June 1, 2017

RE: **CSI Review – Medical Marijuana Control Program: Form and Method of Administration Rules (OAC 3796:8-1-01, 3796:8-2-01, 3796:8-2-02, 3796:8-2-03, 3796:8-2-04, 3796:8-2-05, 3796:8-2-06, and 3796:8-3-01)**

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 eight new rules proposed by the State of Ohio Board of Pharmacy. The rule package was submitted to the CSI Office on May 5, 2017, and the comment period remained open until May 19, 2017. One comment was received during this period.

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 deal with the forms and methods of administration acceptable for medical marijuana. The proposed rules cover topics including, but not limited to, definitions, the list of authorized forms and methods, the petition process for adding new forms and methods, prohibiting forms attractive to children, establishing the 90-day supply, and assignment of product identifiers.

The Board engaged citizens, businesses, advocacy groups, prospective patients and caregivers, industry associations, and the Medical Marijuana Advisory Committee. Through this outreach, 31 comments were received. Eleven of these comments suggested that the 90-day supply limitation be increased or decided by physicians. The Board did not make changes as it believes scientific data support its decision and statute requires the Board to adopt rules establishing limits for a 90-day

supply. Other comments suggested increases in Tier I and Tier II plant material amounts in addition to plant material measured in grams rather than ounces. The Board increased Tier I and Tier II plant material amounts to 8 and 5.3 ounces, respectively, in addition to providing a conversion of ounces to grams in the rules. It also included a terminal patient exception to the 90-day supply limits that allows for those patients diagnosed with a life expectancy of six months or less to receive greater amounts of medical marijuana in their 90-day period. Seven comments were received pertaining to expanding the forms and methods of administration beyond what is listed in the rules. However, House Bill 523 listed the forms and methods that the Board established in these rules and required it to set up a petition process to add new forms and methods. The Board has established the petition process in Ohio Administrative Code (OAC) 3796:8-2-02. From discussions during CSI review and comments received requesting lotions and other topical applications be approved, the Board added lotions, creams, or ointments for topical administration to the list of authorized forms and methods in OAC 3796:8-2-01. The updated rules were provided to CSI on June 1.

These rules will impact cultivators and processors as they will have to pay for proper child-proof packaging, markings for their products, and the \$100 fee for the assignment of the product identifier. This fee is paid for each dose of each medical marijuana strain and product. Additional packaged quantities of previously assigned identifiers do not need to pay the fee again unless something has changed in the product. The BIA prepared by the Board states that the rules are justified because they are required by statute and they establish a unique industry that requires strict regulation for public health and safety. The rules also ensure that patients receive a consistent product and promote the safe use of medical marijuana while avoiding risks associated with theft and abuse. The Board, furthermore, provides flexibility in the rule to allow for an expansion of the list of the acceptable forms and methods through a petition process.

During the CSI public review period, only one comment was submitted. The Board provided its response to this comment on May 22. It did not make changes to the rules based on the comments, but rather, justified the rules either through House Bill 523 obligations or its research and explained where the commenter had misunderstood, such as in the Tier I and II plant material amounts.

The Board 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 Board, 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 should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.