ACTION: Revised

DATE: 03/22/2017 10:17 AM

MEMORANDUM

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

FROM: Tess Eckstein, Regulatory Policy Advocate

DATE: February 10, 2017

RE: **CSI Review – Medical Marijuana Control Program: Cultivator Rules (OAC 3796:1-1-01, 3796:2-1-01 through 3796:2-1-11, 3796:2-2-01 through 3796:2-2-08, 3796:2-3-01, 3796:5-1-01, 3796:5-2-01 through 3796:5-2-03, 3796:5-3-01, 3796:5-4-01, 3796:5-5-01, 3796:5-6-01 through 3796:5-6-03, 3796:5-7-01, 3796:5-8-01)**

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 33 new rules being proposed by the Ohio Department of Commerce. The rule package was submitted to the CSI Office on January 10, 2017, and the comment period remained open until January 27, 2017. The Department submitted a revised BIA on February 10 to revise numbering conventions and to provide more detail on the rules' adverse impacts on regulated entities. Final revisions to the rules were also submitted on February 10.

The proposed rules, which are statutorily mandated in recently-enacted ORC Chapter 3796, make up the first of multiple rule packages that will 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 Department of Commerce is responsible for the administration, implementation, and enforcement of rules pertaining to cultivators, processors, and testing laboratories. The 33 rules in this package deal with cultivators, defined as those who grow, harvest, package, and transport medical marijuana. The proposed rules cover topics including, but not limited to, definitions, obtaining provisional licenses and certificates of operation, transfer of ownership or location, cultivation area expansion, packaging and labeling, inventory control, security, reporting,

inspections, fees, advertising, and prohibited activities.

As cultivators will be the sole entities responsible for the legal growth of marijuana in Ohio, entities that are issued certificates of operation to cultivate medical marijuana will be impacted by the proposed rules, along with any other persons who are therefore prohibited from growing medical marijuana. Potential adverse impacts of the rules include paying application, licensing, and renewal fees; maintaining required proof of working capital and financial responsibility; compiling required information for creating business, operations, quality assurance, security, and financial plans; completing an application; preparing and filing reports; recordkeeping; inspections; laboratory testing; registering medical marijuana products and employees (issuing identification cards); and covering various other costs, such as paying for background checks, performing proper waste removal, meeting security requirements, paying insurance premiums, and providing two licensed employees to accompany each shipment of medical marijuana products. Finally, violations of the rules or ORC Chapter 3796 could result in fines of up to $50,000 per violation.

The BIA prepared by the Department 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 cultivator licenses. The rules also ensure that patients receive a safe and consistent product, protect the health and safety of the public, and provide security for cultivation facilities. The Department, furthermore, provides flexibility in the rule to, beginning September 9, 2018, allow for the issuance of additional licenses for cultivators, if population and patient demand support such an increase. Finally, the rules allow the Department to consider additional factors, aside from weighted criteria for the various plans (e.g. operations plan) that each applicant is required to provide to the Department, when awarding a provisional license. These factors include consideration of principal place of business, environmental plans, employment practices, verification of economically disadvantaged groups, and plans to perform scientific studies.

The Department engaged the general public and the Medical Marijuana Advisory Committee in discussions regarding the proposed rules. As a result of these discussions, the Department received more than 75 early stakeholder outreach comments, the majority of which fit into five categories: the number of provisional licenses issued for Level I (cultivating up to 25,000 square feet of space, unless a request for expansion is approved) and Level II cultivators (cultivating up to 3,000 square feet of space, unless a request for expansion is approved), the Program's ability to scale operations and meet patient demand (specifically, square footage limitations), financial constraints for potential applicants, environmental impact, and packaging and expiration requirements. After reviewing each comment, consulting with industry experts, and speaking with stakeholders, the Department made several revisions to the rules before submitting them to the CSI Office for further review.

Pertaining to the number of available licenses, the Department increased the number of Level II cultivator provisional licenses available to be issued prior to September 8, 2018 (the effective date of the Program) from six to 12, which is consistent with the number of available Level I licenses. The Department also increased the square footage of grow capacity for both Level I (from 15,000 to 25,000 square feet) and Level II (from 1,600 to 3,000 square feet) cultivators. In the same vein, the

Department revised the rules to allow, beginning September 9, 2018, up to two cultivation area expansions: 25,000 square feet for each expansion for Level I cultivators, for a maximum of 75,000 square feet; and 3,000 square feet for each expansion for Level II cultivators, for a maximum of 9,000 square feet. In addition, the Department reduced the levels of surety bond coverage or escrow account balance and included performance triggers that gradually reduce the amounts, until requirements no longer exist. Insurance requirements were also added to the rules. Regarding pesticide use, the Department worked with the Department of Agriculture to determine a list of approved pesticides and fertilizers that can be used for the first 21 days that plants are in the flowering stage. In exchange, the Department implemented a recommendation to test each batch of medical marijuana for pesticides prior to packaging. An applicator license requirement was also removed from the rules. Finally, recognizing environmental concerns, the Department revised the rules to permit composting of facility waste for future use. Similarly, the rules now provide a mechanism for certifying that products meet particular quality and safety standards.

During the CSI public review period, interested parties submitted 49 comments. Most of the comments fit into five general categories: home grow, fees, pesticides, advertising, and a desire to have more Level II licenses and no Level I licenses. In response to these comments, the Department informed the CSI Office that it would make revisions to the rules to address a few instances where rule language could be made clearer, and to remove an unintended restriction on certified physicians from being involved with medical marijuana cultivating operations (the Department intended for the restriction to apply only to physicians who had been issued a certificate to recommend or who had applied for certification). The Department also modified a requirement to provide tax returns, for an applicant and for every person with a financial interest in the applicant, for the three years prior to filing an application. Instead, the requirement will now be satisfied when an applicant submits only tax summary pages for these individuals. Furthermore, the Department limited the applicability of this requirement to persons with a financial interest of one percent or greater. In addition, references to “opaque” were replaced with “light resistant” in relation to product packaging, to enable patients to view a product before purchasing it. Lastly, the Department changed the rule pertaining to fee schedules to clarify that cultivators and processors are required to register each product with the Department but that applicable registration fees are dictated by the State Board of Pharmacy rules.

The Department also explained its rationale for not making other changes that were recommended in submitted comments. Growing medical marijuana at home is not allowed by the legislature; the fees being charged by the Department are directly proportional to the cost of developing the Program, the E-license system, and the seed-to-sale inventory system; and pesticides are not allowed past 21 days into a plant’s flowering stage because pesticides take four to six weeks to leave the plant, although there are already some products that have been approved as safe to use up to the time of harvest. Finally, the Department did not want to eliminate all Level I licenses because in order for this Program to be as successful as possible in its infancy—defined by a safe, consistent supply and the highest quality medical marijuana products—it is important to allow experienced, often larger companies to apply for licenses. The Department anticipates that many Level I license applications will be submitted by Ohioans who have partnered with these existing, experienced companies. The Level II licenses also provide smaller Ohio entities with an opportunity to succeed by ensuring that

they have the same chance to earn licenses as larger, more experienced entities. Furthermore, the reason for limiting available licenses to 12 Level I licenses and 12 Level II licenses is to prevent an oversupply of medical marijuana for the number of patients purchasing it. As mentioned previously, there is no limit to the number of additional cultivator licenses the Department can issue beginning September 9, 2018, as long as population size and patient demand support issuance of these licenses.

After reviewing proposed revisions, the CSI Office engaged in many conversations with the Department to discuss outstanding concerns it felt needed to be addressed to protect regulated entities from unnecessary burden. Simultaneously, the Department met with other outside groups to discuss topics such as insurance and advertising. As a result of these discussions, the Department agreed to make many rule language changes to help clarify intent or reduce burden on cultivators. For example, the Department modified language originally requiring 24-hour recordings from all video cameras to allow for a "24-hour live feed with motion-censored recording capabilities," since this saves cultivators money that would otherwise be spent on infrastructure, bandwidth, and storage costs. Furthermore, the "Criminal records check" rule was revised to clarify that out-of-state applicants are not required to travel to Ohio specifically to be fingerprinted.

The Department also incorporated language to address a concern that the rule requiring insurance coverage, "Cultivator financial responsibility," did not specify which types of coverage were required. To remedy this, the Department added language to specifically require product liability and general liability coverage, assuming "such products are in existence at the time of issuance or the time of renewal for the certificate of operation." Also in this rule, the Department reduced required levels for surety bond coverage and escrow account balance from $1,500,000 to $750,000 for Level I cultivators, and from $150,000 to $75,000 for Level II cultivators. In addition, the Department changed rule language wherever CSI identified potential areas of confusion or misunderstanding.

Aside from changes to rule language, the Department also confirmed that it would provide all informational documents and approved lists before applicants were invited to submit applications. Many commenting stakeholders expressed concern about not having seen the list of approved pesticides, application instructions, and other forms that the Department has provided or will be providing in the near future.

Finally, in response to recommendations from both the CSI Office and impacted stakeholders, the Department eliminated the proposed designated territory structure. The CSI Office and the Department agreed that, although there were some security reasons to require specific numbers of licensees within each territory, the adverse impacts associated with the creation of territories outweighed the benefits. Specifically, this limitation created the risk that patients might not receive the highest quality medical marijuana products, since territory limits could result in high quality cultivators failing to achieve one of three top application scores in a specific territory. Moreover, by limiting the number of provisional licenses and certificates of operation available to be issued by the Department in any designated territory, businesses could incur significant costs to apply and plan for operations in multiple territories.

As noted above, 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 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 Ohio Department of Commerce, Medical Marijuana Control Program should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.

cc: Mark Hamlin, Lt. Governor's Office