5/5/2017

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New Rules – Medical Marijuana Form and Method of Administration Rules

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, 3796:8-3-01

Comments on the proposed rules will be accepted until close of business on **May 19, 2017**. Please send all comments to the following email addresses: MMCPRules@Pharmacy.Ohio.gov; CSIPublicComments@Governor.Ohio.gov.

To view the business impact analysis (BIA) and a complete set of the Ohio Medical Marijuana Control Program draft rules please visit: www.MedicalMarijuana.Ohio.gov/rules.

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CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Board of Pharmacy

Regulation/Package Title: Medical Marijuana Control Program Form and Method of Administration Rules

Rule Number(s): 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, 3796:8-3-01

Date: May 5, 2017

Rule Type: New

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Ohio House Bill 523 of the 131st General Assembly established the Ohio Medical Marijuana Control Program ("the Program"). Outlined in Chapter 3796 of the Revised Code, the responsibilities for the Program are divided between three state agencies. These agencies are the Ohio Department of Commerce ("Department"), State of Ohio Board of Pharmacy, and the State Medical Board of Ohio. The Board of Pharmacy is responsible for the oversight of

authorized forms and methods of administration as well as defining what is attractive to children. This Business Impact Analysis addresses rules that apply to medical marijuana form and method of administration.

- 3796:8-1-01: Defines terms specific to forms and methods of administration
- 3796:8-2-01: Articulates authorized medical marijuana forms and methods of administration.
- 3796:8-2-02: Establishes a petition process through which new forms and methods of administration may be approved by the State Board of Pharmacy
- 3796:8-2-03: Outlines the products that will be considered attractive to children
- 3796:8-2-04: Establishes the quantity of medical marijuana that may be purchased in a 90-day period.
- 3796:8-2-05: Sets forth the procedure for the assignment of a product identifier.
- 3796:8-2-06: Refines the dosing and unit requirements for medical marijuana products authorized for sale at a dispensary.
- 3796:8-3-01: Establishes the fee for the assignment of a product identifier.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   Chapters 119 and 3796 of the Revised Code are the authorizing statutes for these rules.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   While the MMCP rules do not implement a federal requirement, care was taken in the drafting of all MMCP rules to consider the United States Department of Justice drug enforcement priorities.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Not applicable.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The form and method of administration rule set is intended to afford patients access to safe medical marijuana products while mitigating risks of accidental ingestion realized in states that have previously established medical marijuana programs.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of this program will be measured by the availability of safe medical marijuana products and dispensary environments for patients and caregivers. The MMCP rules are designed to be flexible to accommodate the evolving needs of patients, caregivers, and industry.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The Board solicited comments from the public and the Medical Marijuana Advisory Committee (MMAC). Comments were tracked by category—one comment could have more than one category. Tracked in this manner, 31 comments were received. The Board received feedback from many different groups and stakeholders with an interest in the Program, including Ohio citizens, Ohio businesses, advocacy groups, prospective patients and caregivers, and both in-state and out-of-state industry associations. Further, the Board hosted a meeting at which it received feedback from prospective patients and caregivers in Ohio.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

   In general, the feedback received can be categorized into the following areas:

   - 11 comments related to 90-day supply
     - 5 suggested that 90-day supply be decided by physicians and patients
     - 8 suggested an increase in 90-day supply

   - MMAC patient representative suggests an increase to 8 ounces for Tier 1 and 6 ounces for Tier II

   - MMAC comments and at least one public comment asked that plant material be measured in grams rather than ounces

- During the public comment period, concern was also raised regarding the 90-day supply as it relates to patients who are diagnosed with a life expectancy of 6 months or less

As a result of comments received regarding 90-day supply, the following changes were made in the draft rules:

	Tier I Plant Material (0–23% THC)	Tier II Plant Material (over 23% THC)	Patches	Oral Adm.	Vaping
1st Draft	6 oz.	4 oz.	19.8 g	9 g	40.5 g
Revised Draft					
General 90-Day Supply	8 oz.	5.3 oz.	26.6 g	9.9 g	53.1 g
Terminal 90-Day Supply	10 oz.	6.6 oz.	33.3 g	11.7 g	65.7 g

- 7 comments sought to expand forms and methods of administration.
    - Many of the proposed forms and methods of administrations were not included in HB 523. The bill does, however, require the Board to establish a petition process through which new forms and methods may be added. This petition process can be found in rule 3796:8-2-02
    - Although not included in the draft filed with CSI, the Board is examining the availability of clinical data related to lotions and other topical applications as a result of comments received.

The substance of remaining comments varied widely making it difficult to group and summarize.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Rules were developed after benchmarking with regulators in other states, talking with industry experts, and hearing from patients and caregivers registered under other state programs.

An expert panel was also called on to examine an appropriate 90-day supply for medical marijuana across forms and methods of administration. An executive summary detailing the research and findings can be found at medicalmarijuana.ohio.gov/advisory-committee. This executive summary was published with the original draft of the dispensary rules.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

There are no alternative regulations or specific provisions within the regulation to be considered.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The intent of these rules is to ensure patient access to a safe and consistent medical marijuana product. The rules are performance-based in that they set parameters without usurping a physician's discretion to provide instruction for use should the physician determine that such instruction is necessary.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Because the MMCP is a new program, there are no existing rules to duplicate. The Board works closely with the Department of Commerce and State Medical Board to ensure consistency and to eliminate redundancy as the MMCP rules are being created.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the MMCP website. As information related to forms and methods of administration becomes available, it will be shared with the MMAC and with stakeholders through the MMCP website. The Board has staff members available to answer questions by telephone and email to answer questions. The Board also gives presentations to groups and associations seeking updates to the form and method of administration rules. The development of the patient registry, which will be used to track a patient's 90-day supply of medical marijuana.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The scope of impacted business will be Ohio physicians holding a certificate to recommend and licensed medical marijuana entities.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Cultivators and processors will have to invest in materials for proper child-proof packaging and in molds or other materials necessary to establish appropriate demarking.

Cultivators and processors will be required to pay a $100 fee for the assignment of a product identifier. This fee was originally filed with the cultivator rule set, but has been transferred to this rule set.

The product identifier is the MMCP equivalent to a National Drug Code (NDC)—required to report to prescription monitoring programs (PMP) across the country. HB 523 incorporated Ohio's PMP, the Ohio Automated Rx Reporting System, into the state's MMCP. Medical marijuana reported into the PMP, therefore, will need to have a product identifier assigned. In Ohio, this assignment will serve as evidence that the product complies with the statutory and Administrative Code requirements for forms and methods of administration.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

The Board does not have data to provide a quantified potential impact for the reasonable compliance costs associated with compliance with the rules, beyond the fee established in rule.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The regulatory intent of the rules justifies the adverse impact because the manufacturing, possession, sale, and administration of medical marijuana constitute violations of federal drug laws. Accordingly, the MMCP rules establish a unique industry that requires strict regulation for the health, safety, and protection of the public. The State has a compelling interest in promoting safe and temperate use of medical marijuana while avoiding risks associated with the diversion and theft of medical marijuana.

Further, the State of Ohio Board of Pharmacy is required to establish a maximum 90-day supply of medical marijuana. The 90-day supply must be based on both the form of medical marijuana and the tetrahydrocannabinol (THC) content, pursuant to Ohio Revised Code section 3796.04(B)(10).

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

There are no exemptions or alternative means of compliance specific to small businesses.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care or the preparation/distribution of controlled substances is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. What resources are available to assist small businesses with compliance of the regulation?

The Board can be contacted via multiple sources:
The Program website: http://medicalmarijuana.ohio.gov
The Board's office is located at: 77 S. High St., 17th Floor, Columbus, OH 43215