
4/21/2017

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 – Patient and Caregiver Rules

3796:7-1-01, 3796:7-2-01, 3796:7-2-02, 3796:7-2-03, 3796:7-2-04, 3796:7-2-05, 3796:7-2-06, 3796:7-2-07, 3796:7-2-08, 3796:7-2-09, 3796:7-2-10, 3796:7-3-01

Comments on the proposed rules will be accepted until close of business on **May 5, 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 Patient and Caregiver Rules

Rule Number(s): 3796:7-1-01, 3796:7-2-01, 3796:7-2-02, 3796:7-2-03, 3796:7-2-04, 3796:7-2-05, 3796:7-2-06, 3796:7-2-07, 3796:7-2-08, 3796:7-2-09, 3796:7-2-10, 3796:7-3-01

Date: April 21, 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 outlined and 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 promulgating rules related to the registration of medical marijuana patients and caregivers under the Program. This Business Impact Analysis addresses rules that apply to medical marijuana patient and caregivers.

3796:7-1-01: Defines terms specific to the patient and caregiver ruleset.

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3796:7-2-01: Establishes the procedure for placement on the medical marijuana registry as a patient.

3796:7-2-02: Provides eligibility criteria for individuals wishing to serve as a caregiver and limits caregivers to natural persons.

3796:7-2-03: Establishes the procedure for placement on the medical marijuana registry as a caregiver.

3796:7-2-04: Limits the purchase of medical marijuana to registered patients, aged 18 and older, and to registered caregivers.

3796:7-2-05: Provides general rules governing patient and caregiver registration, and possession, maintenance, and destruction of medical marijuana.

3796:7-2-06: Establishes a mechanism to voluntarily surrender a patient or caregiver registration.

3796:7-2-07: Establishes items that must be reported by patients and caregivers.

3796:7-2-08: Establishes grounds for discipline against a patient or caregiver registration.

3796:7-2-9: Allows for summary suspension where the continued access or use would result in a danger of immediate and serious harm to oneself or others.

3796:7-2-10: Describes circumstances under which medical records will be redacted.

3796:7-3-01: Establishes the fees for to be placed on the patient registry. Registration is good for one year and ends on the last day of the month during which it was issued.

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)?

Section 3796.04 of the Revised Code requires the State Board of Pharmacy to “[e]stablish procedures for the issuance of patient or caregiver identification cards.” Moreover, because marijuana is a schedule I controlled substance under federal law, state rules regulating the cultivation, processing, sale, possession, and administration of marijuana are necessary to protect against the risk of criminal charges.

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), end of life caregiver representatives, and prospective Ohio medical marijuana patients and caregivers. Comments were tracked by category—one comment could have more than one category. Tracked in this manner, 47 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. The Board also received input from other state agencies.

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:

- Patient registration process
 - o 7 public comments related to the patient registration process
 - o 1 comment suggested allowing state identification cards as a form of ID. This form of identification was already included in the draft rules.
 - o 1 comment raised concern over the homeless population. Informing those concerned of the accommodations already built into the program by linking the registry identification card to a state-issued ID, addressed this concern.

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- 5 comments generally protested the patient registration process established
 - The Board is statutorily required to issue registration cards to patients and caregivers
 - Registered patients and caregivers are afforded certain statutory protections
 - A physician is required to submit the registration to the Board
- No change was prompted due to comments related to the patient registration process
- Caregiver eligibility
 - 4 public comments related to caregiver eligibility
 - 1 sought clarity in paragraph requiring a patient who previously lacked legal capacity to prove that the patient no longer lacked capacity in order to change caregivers; also raised in subsequent caregiver discussions
 - 2 comments sought clarity in an unspecified manner
 - 1 comment and MMAC member raised concern over the exclusion of parents who are 18, 19, or 20 to serve as caregivers
- Home cultivation
 - 9 comments suggested that home cultivation be included as part of the MMCP
 - Cultivation of marijuana under the MMCP is statutorily limited to entities licensed by the Department of Commerce. No change was made to the draft rules as a result of these comments.
- Registration fees
 - 6 comments related to the fees for patient and caregiver registration
 - All comments suggested that fees were too high or that fees were inappropriate
 - The Board is required to issue patient and caregiver cards
 - Based on best practices in other states, the \$50/year registration fee for patients is below the national average of \$72/year
 - Based on best practices in other states, the caregiver registration fee of \$25/year is below the national average of \$70/year
 - Comments related to registration fees did not result in amended rules

Based on MMAC feedback, public feedback, and discussions between stakeholders and regulators from other agencies, the following changes were made to the draft rules:

- **“Veteran” definition** – The definition of “veteran” was harmonized with the definition used by the Ohio Department of Veteran Services. The definition now includes National Oceanic and Atmospheric Administration, members of the commissioned corps of US Public Health Service, and wartime members of the

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Merchant Marine. It also requires satisfactory service to obtain a reduced registration fee.

- **Terminal illness** – Based on public comments to the form and method of administration rules, language regarding terminally ill patients was added. A unique registration timeline for patients diagnosed with a terminally ill condition was added to the rules.
- **Caregiver eligibility** – Language regarding the proof of legal capacity for patients who previously lacked capacity and who are seeking to change caregivers was removed. Parents of minor patients who are 18, 19, or 20 are authorized to serve as the caregiver for their children.
- **Hospice exception to patient/caregiver ratio** – Based on feedback from hospice representatives and state representatives responsible for enforcing administrative rules related to hospice additional language was built around this already existing hospice exception. Hospice providers who choose to serve as medical marijuana caregivers will register one time each year and not each time a new patient is enrolled. The hospice provider will notify the Board of the enrollment of new medical marijuana patients for whom it will serve as a caregiver.
- **Alternate containers** – Based on feedback from prospective patients and caregivers, the rules were amended to allow patients to carry a portion of medical marijuana in a container provided and labeled by the dispensary.
- **Documents accepted for veteran benefits** – Public comment and consultation with other state agencies suggested expansion of proof of veteran status. Such proof now includes: (1) Department of Defense identification card (active, retired, temporary disability retirement list (TDRL)); (2) DD214 military discharge certificate indicating disposition of discharge; (3) Report of separation from the national archives national personnel records center in St. Louis, Missouri; or (4) Veterans identification card from the department of veterans affairs.

The Board reviewed every comment submitted to the Medical Marijuana Control Program (MMCP) rules address. There were a variety of subjects within the remaining categories that made it difficult to generalize those comments. Some of those comments included:

- General comments regarding the approval or disapproval of certain aspects within the rules
- Questions related to information that will be available through another rule set related to forms and methods of administration
- Suggested changes that would require a statutory change to effect

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- Comments related to regulations falling under the purview of either the State Medical Board or the Department of Commerce

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, hearing from patients and caregivers registered under other state programs, speaking with Ohio hospice representatives, and with prospective Ohio patients and caregivers.

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.*

Performance-based regulation is not applicable to the registration of patients with qualifying conditions and their caregivers.

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

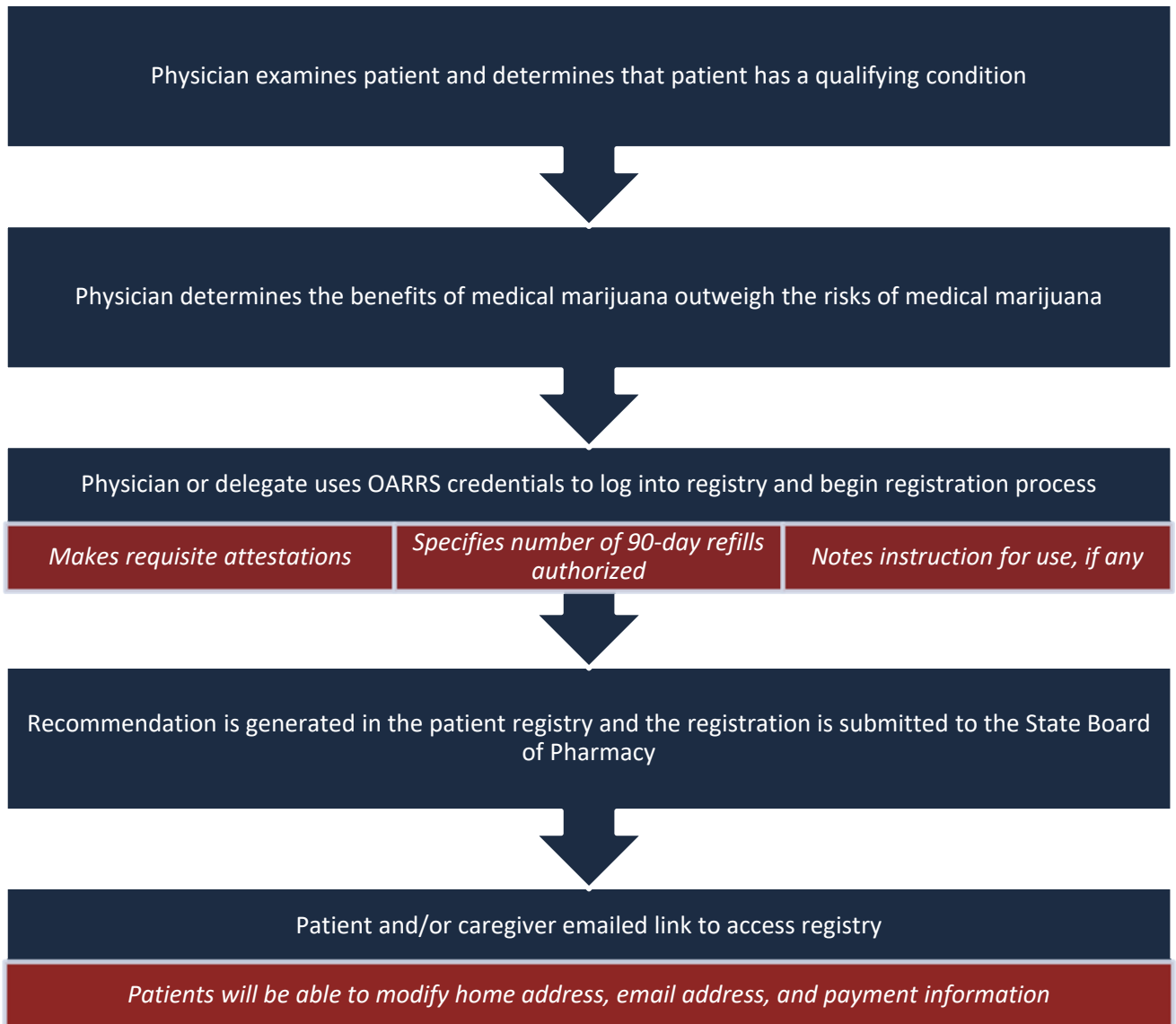
Because the MMCP is a new program, there are no existing rules to duplicate. The Board works closely with the Department of Commerce and State Medical Board to ensure consistency and to eliminate redundancy as the MMCP rules are being created. For instance, with the cultivator rules, a single, Program-wide definitions section was filed.

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 patient registration 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 groups and associations seeking updates to the patient and caregiver rules. The development of the patient registry and production of registry identification cards is well underway. An overview of the registration process is illustrated below.

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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 would 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

Patients and caregivers will have to have an in-person examination with a physician with a certificate to recommend once each year in order to receive a recommendation for medical marijuana. The recommending physician is statutorily required to submit the patient and/or caregiver registration to the Board. Under the rules, this can be completed by the physician during an annual office visit using the same credentials already used by physicians to log onto OARRS. Patients will remit a \$50 registration fee and caregivers will remit a \$25 registration fee.

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 fees established in rule.

While the ultimate adverse impact for a violation of the Board’s rules could be suspension, revocation, or rejection of patient or caregiver registration, the Board intends to work to assist and educate patients and caregivers to avoid such repercussions.

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

The regulation of medical marijuana is new to Ohio. The patient and caregiver rule set is designed to provide a balanced, transparent, and accountable method for individuals and to obtain and maintain patient and caregiver registration. 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

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establishes 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.

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 registrant or 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