5/8/2020

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.

Amended:

- **3796:7-1-01:** Provides the definitions for the rule chapter on medical marijuana patients and caregivers.
- **3796:7-2-01:** Provides for a process for medical marijuana patient registration.
- **3796:7-2-04:** Establishes the process for the purchase of medical marijuana.
- **3796:7-3-01:** Establishes the fee structure for patients and caregivers.
- **3796:8-1-01:** Provides the definitions for the medical marijuana form and method chapter.
- **3796:8-2-03:** Defines forms and methods of medical marijuana that may be attractive to children.
- **3796:8-2-06:** Provides the requirements for portions, dosing, and units of medical marijuana sold at a dispensary.

New

- **3796:8-2-04:** Establishes the maximum 90-day supply for all approved forms of medical marijuana. (**NOTE:** The current rule will also be rescinded).

Comments on the proposed rules will be accepted until close of business on **May 25, 2020**.

REMINDER FOR THOSE SUBMITTING COMMENTS

- Commenters are reminded that comment submissions may be subject to release under Ohio public records laws.

- Patients should focus on providing comments related to the content of the rule. Patients are not required to identify themselves as patients nor provide their names or medical marijuana registration information when submitting comments.

- The Board cannot change any provisions relating to an employee's use of medical marijuana, specifically the following provisions of Ohio law:
  - Nothing in the law requires an employer to accommodate an employee's use of medical marijuana; and
  - The law does NOT prohibit an employer from refusing to hire, discharging, or taking an adverse employment action because of a person's use of medical marijuana.

Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information:

Cameron McNamee, Director of Policy and Communications,
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Regulation/Package Title (a general description of the rules' substantive content):

Medical Marijuana

Rule Number(s): 3796:7-1-01, 3796:7-2-01, 3796:7-2-04, 3796:7-3-01, 3796:8-1-01, 3796:8-2-03, 3796:8-2-04, 3796:8-2-06

Date of Submission for CSI Review: 5/8/2020

Public Comment Period End Date: 5/25/2020

Rule Type/Number of Rules:

New/_X_ rules — No Change/____ rules (FYR? ___)

Amended/_X_ rules (FYR? _Y_) — Rescinded/_X_ rules (FYR? _Y_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing

regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

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

   3796:7-1-01: Provides the definitions for the rule chapter on medical marijuana patients and caregivers. The rules are being amended to standardize terms across all Board of Pharmacy rules (e.g. changing stale to abandoned). **NOTE:** *The definition of veteran is being removed because the definition of veteran is already tied to approved forms of veteran identification established in rule 3796:7-3-01 of the OAC.*

   3796:7-2-01: Provides for a process for medical marijuana patient registration. The rule is being amended to require patients with court-appointed legal guardians to obtain the consent for treatment from their court-appointed legal guardian. As medical marijuana must be consumed in the state, the rule requires Ohio patients to be Ohio residents. As such, the amended rule removes the option to present a passport to register but provides the Board

additional flexibility to approve new forms of identification. Lastly, the rule removes the requirement that terminally ill patients are recertified as terminal every six months. The amended rule provides terminally ill patients the same registration period as other patients (i.e. one year).

3796:7-2-04: Establishes the process for the purchase of medical marijuana. The amended rule removes the option to present a passport to register but provides the Board additional flexibility to approve new forms of identification. Codifies Board policy on how to calculate a patient's 90-day supply.

3796:7-3-01: Establishes the fee structure for patients and caregivers. Adds individuals who are receiving disability benefits from a state retirement system as qualifying for indigent registration status. Adds state veteran cards as a method for registering a veteran.

3796:8-1-01: Provides the definitions for the medical marijuana form and method chapter. Adds terminology used throughout the chapter and deletes the definition of tier I and tier II plant material.

3796:8-2-03: Defines forms and methods of medical marijuana that may be attractive to children. The rule is being amended to require all medical marijuana packaging to include a universal symbol denoting it contains marijuana. Also states that medical marijuana that resembles commercially available cookies, candies, or other confections is also considered attractive to children.

3796:8-2-04: More than 50 percent of the rule was being amended and therefore the rule is being rescinded and replaced with a new rule. The new rule establishes the maximum 90-day supply for all approved forms of medical marijuana as well as consolidates plant material into a single category (i.e. removes tier I and tier II medical marijuana). The rule also makes modifications to the whole day units in which medical marijuana must be sold. The following three tables illustrate the changes compared to the current rule:

Table 1. Current 90-Day Supply

Type of Medical Marijuana	Current 90-Day Supply	Current Whole Day Unit
Plant Material Tier 1 (23% THC or less)	8 oz (226.8 grams)	1/10 oz / 2.83 grams
Plant Material Tier 2 (exceeds 23% but no more than 35%)	5.3 oz (150.3 grams)	1/10 oz / 2.83 grams
Oils for Vaping	53.1 grams	590 mg
Edibles	9.9 grams	110 mg
Ointments and Creams	26.55 grams	295 mg

Table 2. Proposed 90-Day Supply for Non-Terminally Ill Patients

Type of Medical Marijuana	Proposed 90-Day Supply	Proposed Whole Day Unit
Plant Material (consolidated into a single category)	8 oz (226.8 grams)*	2.52 grams*
Oils for Vaping	53.1 grams	590 mg
Edibles	9.9 grams	110 mg
Ointments and Creams	26.55 grams	295 mg

*Only plant material has been changed for non-terminally ill patients.

Table 3. Current 90-Day Supply – Terminally Ill

Type of Medical Marijuana	Current 90-Day Supply	Current Whole Day Unit
Plant Material Tier 1 (23% THC or less)	10 oz (283.5 g)	1/10 oz / 2.83 grams
Plant Material Tier 2 (exceeds 23% but no more than 35%)	6.6 oz (187.1 g)	1/10 oz / 2.83 grams
Oils for Vaping	65.7 grams / 65,700 mg	0.59 g / 590 mg
Edibles	11.7 g / 11,700 mg	0.11 g/ 110 mg
Ointments and Creams	33.3 g / 33,000 mg	0.295 g / 295 mg

Table 4. Proposed 90-Day Supply – Terminally Ill

Type of Medical Marijuana	Proposed 90-Day Supply	Proposed Whole Day Unit
Plant Material	8.9 oz (252.3 g)**	2.52 grams
Oils for Vaping	59 g / 59,900 mg**	0.59 g / 590 mg
Edibles	11 g / 11,000 mg**	0.11 g/ 110 mg
Ointments and Creams	29.5 g / 29,500 mg**	0.295 g / 295 mg

**The 90-day supply for terminally ill patients is being standardized to provide patients an extra 10-day supply of product compared to those who are not terminally ill.

3796:8-2-06: Provides the requirements for portions, dosing, and units of medical marijuana sold at a dispensary. Rule is being amended to require patches be labeled with total target THC and CBD content. Additionally, the rule is providing additional flexibility to cultivators and processors by permitting a product to be within 10 percent of the total target THC and CBD (as opposed to the current 5 percent requirement). The rule also incorporates current Board of Pharmacy policy about products containing trace amounts of THC/CBD in certain medical marijuana products.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Section 3796.04 authorizes the Board of Pharmacy to adopt rules governing the operation of the medical marijuana program specific to patients/caregivers, forms and methods of medical marijuana, and the operation of medical marijuana dispensaries. The following statutes amplify this authority: 3796.06, 3796.08, 3796.14, 3796.16, 3796.22 & 3796.23.

4. **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.

   As marijuana is considered a schedule I controlled substance, the rules governing the medical marijuana program do not implement any federal requirements.

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

   Section 3796.04 of the Revised Code requires the State Board of Pharmacy to establish rules necessary to govern the operation of the medical marijuana program as it pertains to dispensaries, patient/caregivers, and forms and methods of medical marijuana.

   Moreover, because marijuana is a schedule I controlled substance under federal law, state rules regulating the sale, possession, and administration of marijuana are necessary to protect against the risk of criminal charges.

6. **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 establish rules necessary to govern the operation of the medical marijuana program as it pertains to dispensaries, patient/caregivers, and forms and methods of medical marijuana. Without these regulations, the Board would not be able to implement and operate a safe medical marijuana program that meets the requirements of Ohio law.

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

The success of these regulations will be measured by licensee/registrant compliance with the rules and reduction in the overall questions from licensees/registrants regarding the provisions of the rules, specifically as it relates to the calculation of a patient's 90-day supply.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **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.

   All of the rules were initially published to the Ohio Medical Marijuana Control Program website for a round of public comments. Additionally, dispensary representatives and members of the Ohio Medical Marijuana Advisory Committee were also consulted on specific provisions relating to the calculation of a patient's 90-day supply (OAC 3796:7-2-04 and 3796:8-2-04).

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

    The Board made the following changes based upon feedback provided by the stakeholders:

    - Removed plant material tiers in OAC 3796:8-2-04 based upon feedback provided by patients, industry representatives and members of the Advisory Committee.
    - Extended the range of target THC and CBD from 5% to 10% based upon industry feedback.
    - Established the 45-day fill periods in OAC 3796:7-2-04 based upon feedback from patients, dispensary representatives and members of the Advisory Committee.

Additionally, prior to filing with CSI, the rules were also reviewed and approved by members of the Board of Pharmacy.

11. 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?

The Board consulted with pharmacists who were part of an initial expert review panel on establishing forms and methods of medical marijuana. Additionally, the Board also reviewed rules and policies from other states operating medical marijuana programs.

12. 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?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the registration of patients/caregivers and forms and methods of medical marijuana, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. 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 regulations are not applicable to the registration of patients with qualifying conditions and their caregivers. They also do not lend themselves to ensuring uniformity of medical marijuana products sold at licensed dispensaries.

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

Board staff reviewed the proposed rules to ensure that the regulation does not duplicate another existing regulation.

15. 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.

Implementation of the changes in the rules will be accompanied by guidance documents for patients, caregivers, and dispensary employees. Additionally, the Board, as it has done with previous changes, will host several webinars with dispensary staff to ensure they are able to implement the proposed rule changes.

The Board will also monitor data reported to OARRS by medical marijuana dispensaries to ensure the rules are being applied consistently. In addition, Board of Pharmacy medical

marijuana field agents will also be responsible for ensuring the rules are being applied consistently.

Adverse Impact to Business

16. 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; and

- Medical marijuana patients and caregivers;
- Medical marijuana dispensaries; and
- Medical marijuana cultivators and processors.

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

- Patients and caregivers will have to 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. Additionally, patients seeking indigent or veteran status must submit additional documentation to the Board. (**NOTE:** The impact to patients/caregivers and recommending physicians is not the result of the proposed rule amendments).

- Cultivators and processors who market plant material will have to make modifications to their labeling and package sizes, as the size of plant material packaging will change from 2.83 gram to 2.52 grams and all packaging must contain the universal symbol for marijuana. Additionally, cultivators and processors may have to adjust processes to allow for the additional flexibility provided in OAC 3796:8-2-06 for target THC and CBD requirements.

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 specific data to provide a quantified potential impact for the reasonable compliance costs associated with compliance with the rules beyond the fees established in rule. However, the Board does expect that changes to plant material packaging will result in increased, one-time monetary and staff training costs for cultivators and processors complying with the new package size and labeling requirements for plant material products. Additionally, the Board does expect to see compliance costs for dispensaries in order to re-train staff on the new days' supply calculations and other changes to the rules.

- However, to lessen the burden on the modifications to packaging sizes for plant material, the Board has implemented a 90-day grace period where plant material in the current package size (2.83 grams) may still be sold by dispensaries. The goal is to allow for a transition period for the new packaging to reduce the overall costs to MMCP licensees.

- Additionally, the Board expects that because plant material will no longer be sold in two separate tiers, the resulting rule change may reduce some costs to cultivators and processors.

17. 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

18. 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.

19. 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.

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

The Board has multiple resources to assist small business including:

- The Medical Marijuana Control Program website: http://medicalmarijuana.ohio.gov. As stated previously in this document, the Board will be issuing new guidance documents and hosting webinars to assist licensees in complying with the rules.
- Each dispensary is provided an assigned Board of Pharmacy field agent to answer any questions that dispensary operators may have.
- The Board has several dedicated office staff available to field questions from all licensees and registrants.

3796:7-1-01 Definitions.

(A) “Administer” or “administration” means the direct introduction of medical marijuana into the body of a human, whether through inhalation, ingestion, or any other means.

(B) “Business day” means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the state board of pharmacy is not open for business.

(C) “Terminal illness” means a qualifying condition for which a prospective patient has received a diagnosis for a life expectancy of six months or less if the illness runs its normal course.

(D) “Refuse to grant or renew” means to deny an original or continued registration for a period of at least twelve months. After twelve months or such period of time as the individual board order may require, a patient or caregiver or an individual who desires to attain such status by registration, and whose registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new registration in accordance with Chapter 3796. of the Revised Code and this division. An individual who desires to attain patient or caregiver status by registration and whose registration the state board of pharmacy has refused to grant or renew must meet any requirements established by the board.

(E) “Registry identification card” collectively refers to cards issued by the state board of pharmacy as evidence that an individual is registered as a patient or caregiver.

(F) “Revoke” means to take action against a registration rendering such registration void and such registration may not be reissued. "Revoke" is an action that is permanent against the registration and registrant.

(G) “~~Stale~~ Abandoned registration” means a submission to register as a patient or caregiver where the submitter fails to complete all submission requirements within ninety calendar days of the initiation of a registration by a physician, and after being notified by the state board of pharmacy, subject to the factors that would otherwise remove the submitter from consideration under Chapter 3796. of the Revised Code or this division. An individual forfeits all fees associated with ~~a stale~~an abandoned registration submission. The state board of pharmacy shall not be required to act on any ~~stale~~ abandoned registration and the registration may be destroyed by the board staff. If the registration is ~~stale~~abandoned, the submitter shall be required to reapply for registration in accordance with Chapter 3796. of the Revised Code and this division, in effect at the time of resubmission.

(H) “Suspend” means to take action against a registration rendering such registration without force and effect for a period of time as determined by the state board of pharmacy.

~~(I) “Veteran” means any person who has completed service in the armed forces, including the national guard of any state, or a reserve component of the armed forces, who has been discharged under honorable conditions from the armed forces or who has been transferred to the reserve with evidence of satisfactory service.~~

Commented [cm1]: NOTE: This definition is being removed because the definition of veteran is already tied to approved forms of veteran identification established in rule 3796:7-3-01 of the OAC.

3796:7-2-01 Procedure for patient registration.

(A) Before medical marijuana may be dispensed to or for, possessed by or for, or administered by or for a prospective patient, the prospective patient must be placed on the registry established by the state board of pharmacy in accordance with section 3796.08 of the Revised Code.

(B) To qualify for placement on the registry, a prospective patient must:

(1) Establish and maintain a bona fide physician-patient relationship with a recommending physician who shall submit a complete patient registration submission;

(2) Receive a diagnosis or confirmation of a qualifying condition from the recommending physician;

(3) Consent to treatment with medical marijuana. If the patient is a minor or individual with a court-appointed legal guardian, the prospective patient's parent or legal representative shall consent to treatment with medical marijuana;

(4) Remit to the state board of pharmacy the required fee; and

(5) Unless otherwise provided pursuant to a reciprocal agreement under division (A) of section 3796.16 of the Revised Code, be an Ohio resident.

(C) A physician with whom a prospective patient has a bona fide physician-patient relationship, or, subject to the limitations under section 3796.08 of the Revised Code, the physician's delegate, shall submit the patient registration. For a registration submission, related to a patient who is eighteen years of age or older, to be considered complete, a completed recommendation from a physician, applicable patient registration fee, and the following items must be submitted to the state board of pharmacy in a manner suitable to the board:

(1) ~~Patient~~Patient's full name, residential address, telephone number, date of birth, electronic mail address, and qualifying condition(s);

(2) Patient's government-issued identification number (such as driver's license number). Patients and caregivers must present a recommending physician with an unexpired ~~United States passport, United States passport card, state-issued~~ driver's license~~;~~ or other ~~state-issued~~ identification issued by the Ohio bureau of motor vehicles (BMV) or other identification proving Ohio residency as approved by the board of pharmacy;

(3) Recommending physician's full name (first name and last name);

(4) Drug enforcement administration physician identification number and medical license number issued by the state medical board;

(5) Recommending physician's certificate to recommend identification number issued by the state medical board;

(6) Date recommendation was issued by the recommending physician;

(7) Recommending physician's business address, telephone number, and email address;

(8) Indication whether the recommendation is new or a renewal;

(9) The following patient attestations:

(a) The physician has explained to the individual the possible risks and benefits associated with the use of medical marijuana;

(b) The individual consents to treatment with medical marijuana; and

(c) The individual agrees to comply with Chapters 2925. and 3796. of the Revised Code and this division.

(10) An attestation from the recommending physician in accordance with division (A)(2) of section 3796.08 of the Revised Code; and

(11) Such other information as the state board of pharmacy may reasonably require.

(D) If a prospective patient is younger than eighteen years of age or has a court-appointed legal guardian, a patient registration submission must be accompanied by a caregiver registration submission in accordance with rule 3796:7-2-03 of the Administrative Code, before it will be considered complete. Patients who become eighteen years of age during the time period in which their registration is valid may apply for a new registration either immediately or in accordance with the renewal process under paragraph (K) of this rule. A submission from a patient that includes all information found in paragraph (C) of this rule, shall be considered complete.

(E) A complete patient registration submission must be received by the state board of pharmacy within ninety calendar days of the date on which the recommendation was created by the prospective patient's recommending physician. Failure to comply with this requirement will void the recommendation and the person's registration shall be deemed abandoned.

(F) Applications submitted by an applicant diagnosed with a terminal illness shall be approved or denied within ten business days. To qualify for registration as a patient diagnosed with a terminal illness, the prospective patient's registration submission shall include with the registration submission, an attestation specifying that the patient has a terminal illness, submitted by the patient's recommending physician.

~~(1) The registration of a patient who is registered as someone who is terminally ill shall be valid from the date of issuance and expire after six months.~~

~~(2) If after a period of six months, a patient's terminally ill condition continues and the patient's recommending physician continues to recommend medical marijuana, the recommending physician shall confirm that patient's condition continues to be a terminal illness.~~

~~(3) The registration for patients whose terminally ill condition has been confirmed after a period of six months, pursuant to paragraph (F)(2) of this rule, shall expire in accordance with paragraph (I) of this rule.~~

(G) If a registration submission is determined to be inaccurate or incomplete, the state board of pharmacy shall send the prospective patient notice of the deficiency. If the deficiency is not corrected within ninety calendar days from the date that the registration was submitted by a physician, the submission shall be considered ~~stale~~abandoned.

(H) Prospective patients must provide proof of Ohio residency to their recommending physician or the physician's delegate during the physician's initiation of the registration submission process. Proof of Ohio residency shall include one of the following:

(1) The prospective patient's unexpired Ohio driver's license;

(2) The prospective patient's unexpired Ohio identification card issued by the Ohio bureau of motor vehicles (BMV); ~~or~~

(3) ~~The prospective patient's unexpired United States passport or United States passport card~~Any other identification proving residency as approved by the board of pharmacy~~.~~

(I) A patient registration shall be valid from the date of issuance and expire one year later, on the last day of the month it was issued~~, unless issued pursuant to paragraph (F) of this rule~~.

(J) The state board of pharmacy shall send a notification to each patient forty-five calendar days before the expiration date on the patient's registry identification card.

(K) To maintain a valid patient registration, a patient must annually renew, before the expiration date stated on the patient's registry identification, a patient registration, in accordance with this rule. Renewal submissions, fees, and required documentation may be submitted up to thirty calendar days before the registration will expire. Failure to renew a patient registration will result in an automatic ~~suspension~~expiration of the registration card.

3796:7-2-04 Purchase of medical marijuana.

(A) A patient or caregiver may only purchase medical marijuana pursuant to a valid and active recommendation issued by a physician pursuant to rule 4731-32-03 of the Administrative Code.

(B) No patient under eighteen years of age shall purchase medical marijuana.

(C) Patients and caregivers must provide their registry identification card and photographic identification before entering the dispensary department. Acceptable photographic identification includes:

(1) An unexpired Ohio ~~state~~ driver's license;

(2) An unexpired Ohio identification card issued by the Ohio bureau of motor vehicles (BMV); or

(3) ~~An unexpired United States passport or United States passport card~~Other identification approved by the board of pharmacy.

(D) The identification number on the photographic identification provided to a dispensary employee must be identical to the identification number included in the patient or caregiver's registration record.

(E) Before purchasing medical marijuana, patients and caregivers must provide the dispensing employee their registry identification card and photographic identification described in paragraph (C) of this rule.

(F) A ~~patient may purchase any portion of their ninety-day supply at any time except that no patient shall receive more than a ninety-day supply in a ninety-day period~~patient's ninety-day recommendation shall be divided into two forty-five-day fill periods, except that the first fill period of a patient's new recommendation shall be forty-six days. A patient may purchase up to a forty-five-day supply or, if applicable a forty-six-day supply for the first fill period of a new recommendation, at any time during a fill period.

(G) ~~A~~ Except as provided in paragraph (G)(1) of this rule, a caregiver may obtain no more than a ~~ninety-day~~forty-five day supply of medical marijuana in ~~a ninety-day~~any forty-five day fill period on behalf of a single patient. ~~A caregiver shall purchase no more than the aggregate amount of medical marijuana authorized for each of the caregiver's patients.~~

(1) A caregiver may purchase up to a forty-six-day supply in a forty-six-day period on behalf of a single patient during the patient's first fill period of a new recommendation.

(2) A caregiver shall purchase no more than the aggregate amount of medical marijuana authorized for each of the caregiver's patients.

3796:7-3-01 Medical marijuana patient and caregiver fee structure.

(A) The following non-refundable fees shall be paid to the state board of pharmacy:

(1) The annual fee for a patient registration is fifty dollars. One application fee must be submitted with each application.

(2) The annual fee for a caregiver registration is twenty-five dollars. One application fee must be submitted with each application.

(B) The state board of pharmacy may reduce registration fees to fifty per cent of the full registration price for a prospective patient who qualifies for indigent or veteran status, and any prospective caregiver for such a patient. To qualify the patient must be a patient who is:

(1) Enrolled in the federal "Social Security Disability Income" (SSDI) or the "Supplemental Security Income" (SSI) disability programs. To qualify for a reduced registration fee due to enrollment in either SSDI or SSI programs, the prospective patient shall submit to the state board of pharmacy a copy of a letter or other documentation from the United States social security administration demonstrating the:

(a) Identity of the patient; and

(b) Amount of monthly SSDI and SSI benefits to be received by the prospective patient during the current year of the registration submission.

(2) Enrolled in a state retirement system and receiving monthly disability income from the retirement system. Examples include: a state public employees retirement system, a state teacher retirement system, and a police or fire retirement system. To qualify for a reduced registration fee due to enrollment in a state retirement disability program, the prospective patient shall submit to the state board of pharmacy a copy of a letter or other documentation from the retirement program demonstrating the:

(a) Identity of the patient; and

(b) Amount of monthly disability benefits to be received by the prospective patient during the current year of the registration submission.

~~(2)~~ (3) A veteran. To qualify for a reduced registration fee due to veteran status, the prospective patient shall submit to the state board of pharmacy a copy of any of the following documents. ~~All~~ Except for documents listed in paragraphs (B)(3)(d) and (B)(3)(e) of this rule, all acceptable proof documents~~, except veterans' identification card,~~ must show the veteran status as honorable, general, general under honorable conditions, or discharged or released under any conditions other than dishonorable.

(a) Department of defense identification card (active, retired, temporary disability retirement list (TDRL));

(b) DD214, DD215, or national guard bureau (NGB) military discharge certificate indicating disposition of discharge;

(c) Report of separation from the national archives national personnel records center in St. Louis, Missouri; ~~or~~

(d) Veterans identification card from the department of veterans' affairs~~.~~; or

(e) Veterans identification card issued in accordance with section 317.214 of the Revised Code.

(4) The board may approve additional documentation to determine if a prospective patient qualifies for veteran or indigent status.

3796:8-1-01 Definitions.

For purposes of rules promulgated pursuant to Chapter 3796. of the Revised Code:

(A) "~~Child-proof~~Child-resistant" means the packaging standards described in 16 C.F.R. 1700.15 (as in effect on February 1, 2017).

(B) "Edible medical marijuana" means a product that:

(1) Contains marijuana or an extract thereof;

(2) Is intended for human consumption by oral administration; and

(3) ~~Are~~Is presented in the form of foodstuffs.

(C) "THC" means delta-9-tetrahydrocannabinol.

(D) "THCA" means delta-9-tetrahydrocannabinolic acid.

(E) "Total target THC" means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC (i.e., Total target THC = (% THCA x 0.877) + % THC).

(F) "CBD" means cannabidiol.

(G) "CBDA" means cannabidiolic acid.

(H) "Total target CBD" means the sum of the percentage by weight of CBDA multiplied by 0.877 plus the percentage by weight of CBD (i.e., Total target CBD = (% CBDA x 0.877) + % CBD).

~~(C) "Tier I medical marijuana" means plant material with a THC content of twenty-three per cent or less.~~

~~(D) "Tier II medical marijuana" means plant material with a THC content that exceeds twenty-three per cent and contains no more than thirty-five per cent THC.~~

3796:8-2-03 Forms and form variations considered attractive to children.

(A) All medical marijuana accepted by a dispensary shall be packaged in a ~~child-proof~~child-resistant container.

(B) All medical marijuana accepted by a dispensary must be marked with a universal symbol that denotes the product contains medical marijuana as an ingredient, on the outside package label of each individual unit.

~~(B)~~ (C) Pursuant to division (C) of section 3796.06 of the Revised Code, the following medical marijuana products are prohibited as attractive to children:

(1) Any product bearing any resemblance to a cartoon character, fictional character whose target audience is children or youth, or pop culture figure;

(2) Any product bearing a reasonable resemblance to a product available for consumption as a commercially available candy, cookie, or other confection;

(3) Any product whose design resembles, by any means, another object commonly recognized as appealing to, or intended for use by, children;

(4) Any product whose shape bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings;

(5) Any medical marijuana product that otherwise targets persons under the age of eighteen.

~~(C)~~ (D) Pursuant to division (C) of section 3796.06 of the Revised Code, the following restrictions apply to the administration of medical marijuana by vaporization, as attractive to children:

(1) Characterizing flavors, except those intended to mimic marijuana strains, are prohibited from all products intended for use in the vaporization of medical marijuana;

(2) Vaporization is not an authorized method of administration for registered patients under the age of eighteen.

3796:8-2-04 **Quantity of medical marijuana that may be purchased by a patient or caregiver. (RESCIND CURRENT VERSION OF 3796:8-2-04)**

(A) A patient and a patient's caregiver(s) may collectively purchase no less than a whole day unit at a single time. Except as provided in paragraph (D) of this rule, a whole day unit shall equal the following amounts for each authorized form of medical marijuana:

Authorized Form of Medical Marijuana	Whole Day Unit
Plant material	2.52 grams
Patch for transdermal administration, lotion, cream, or ointment	Up to 295 milligrams of THC
Oil, tincture, capsule, or edible for oral administration	Up to 110 milligrams of THC
Oil for vaporization	Up to 590 milligrams of THC

(B) A patient and the patient's caregiver(s) may collectively purchase no more than a ninety-day supply in accordance with the two forty-five-day fill period process established in rule 3796:7-2-04 of the Administrative Code. Ninety whole day units, aggregated across forms purchased, shall constitute a ninety-day supply of medical marijuana. A patient or caregiver may not purchase more whole day units of medical marijuana than days remaining in their fill periods as set forth in rule 3796:7-2-04 of the Administrative Code. A ninety-day supply is defined by form as follows:

Authorized Form of Medical Marijuana	90-Day Supply
Plant material	8 oz or 226.8 grams
Patch for transdermal administration, lotion, cream, or ointment	26.55 grams of THC
Oil, tincture, capsule, or edible for oral administration	9.9 grams of THC
Oil for vaporization	53.1 grams of THC

(C) Notwithstanding paragraph (B) of this rule, a patient who is diagnosed with a terminal illness and the patient's caregiver(s) may collectively purchase no more than a ninety-day supply in accordance with the two forty-five-day fill period process established in rule 3796:7-2-04 of the Administrative Code. Ninety whole day units, aggregated across forms purchased, shall constitute a ninety-day supply of medical marijuana. A patient or caregiver may not purchase more whole day

units of medical marijuana than days remaining in their fill periods as set forth in rule 3796:7-2-04 of the Administrative Code. A ninety-day supply for patients diagnosed with a terminal illness is defined by form as follows:

Authorized Form of Medical Marijuana	90-Day Supply (Terminal Illness)
Plant material	8.9 oz or 252.3 grams
Patch for transdermal administration, lotion, cream, or ointment	29.5 grams of THC
Oil, tincture, capsule, or edible for oral administration	11 grams of THC
Oil for vaporization	59 grams of THC

(D) For ninety days from the effective date of this rule, a whole day unit of plant material shall consist of either:

(1) Two and eighty-three hundredths grams; or

(2) Two and fifty-two hundredths grams.

3796:8-2-06 Portions, dosing, and units of medical marijuana sold at a dispensary.

To be eligible for sale by a dispensary:

(A) Edible liquids containing multiple portions, or doses, of medical marijuana shall be packaged in a structure that uses a single mechanism to achieve both ~~child-proof~~child-resistant properties and accurate pouring measurement of portions, or doses. The measurement component shall be included within the ~~child-proof~~child-resistant cap or closure of the bottle and cannot be a separate component.

(B) No single portion or dose of medical marijuana in the following forms shall exceed fifty milligrams of THC:

(1) Oil, tincture, capsule, or edible form for oral administration; and

(2) Patches for transdermal administration.

(C) Each portion or dose of medical marijuana shall be clearly demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single portion or dose.

~~-~~(D) Each portion or dose of medical marijuana in patch form must be individually marked with the total target THC and CBD content indicated in the product identifier assignment application.

~~(D)~~ (E) Each portion or dose of medical marijuana shall contain not less than ninety ~~five per cent~~ percent (90%) or no more than one hundred ~~five~~ ten ~~per cent~~ percent (110%) of the concentration of total target THC~~, THCA,~~ and CBD~~, or CBDA~~ content indicated ~~on the label~~ in the product identifier assignment application. For plant material, a total THC and CBD concentration of less than three-tenths of one percent (.3%) will be considered as having zero percent (0%) THC or CBD content. For processed forms of medical marijuana, a total CBD concentration of less than one-tenth of one percent (.1%) shall be consider as having zero percent (0%) CBD content. There is no zero percent (0%) threshold for THC~~%~~ in processed forms of medical marijuana.