



STATE OF
OHIO
BOARD OF PHARMACY



State of Ohio Board of Pharmacy Form and Method of Administration Rules for Public Comment

Posted: December 12, 2019

Overview

As one of three state agencies responsible for developing, implementing and overseeing the Ohio Medical Marijuana Control Program, the Board of Pharmacy is tasked with developing rules that will govern the authorized forms and methods of administering medical marijuana. The guiding principles of the program are to develop rules that are 1) patient-centered and safe; 2) responsive, data-driven and transparent; 3) flexible, scalable, and sustainable; and 4) characterized by consistency, integrity, and collaboration across one program.

The Board of Pharmacy is currently accepting public input on draft form and method of administration rules. The draft rules begin on the next page of this document.

How can I provide comments?

Written comments will be accepted until **5 p.m. ET on January 10, 2020.**

Comments submitted after the deadline will not be considered. All comments should be submitted via email to: MMCPRules@pharmacy.ohio.gov.

When preparing your comments you are invited to:

- Include "Form and Method of Administration Rules" in your subject line
- Explain your views as clearly as possible
- Describe any assumptions used
- Provide any technical information and/or data used to support your views
- Explain how you arrived at your estimate for potential burdens, benefits or costs
- Provide specific examples to illustrate your views
- Offer alternatives

Next Steps

The medical marijuana form and method of administration rules will follow the standard rule development process. After receiving input from the Medical Marijuana Advisory Committee and the public, the rules will be submitted to the Common Sense Initiative, then the Joint Committee on Agency Rule Review.

The public can comment at several points throughout the rule development process. The first opportunity is December 12th – January 10th. For more information on providing comments, please visit medicalmarijuana.ohio.gov/rules.

For more information on the Medical Marijuana Control Program website, including how to sign up for program updates, visit: medicalmarijuana.ohio.gov.

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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) “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.

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3796:8-2-01 Authorized medical marijuana forms and methods of administration.

- (A) Pursuant to section 3796.06 of the Revised Code, approved medical marijuana products include the following forms and routes of administration:
- (1) Oil, tincture, capsule, or edible form for oral administration;
 - (2) Metered oil or solid preparation for vaporization;
 - (3) Patches for transdermal administration or lotions, creams, or ointments for topical administration; and
 - (4) Plant material for administration with the use of vaporizing devices.
- (B) The following limitations apply to vaporizing devices used to administer medical marijuana:
- (1) No vaporizing device, the design of which places medical marijuana in direct contact with the device's heating element, may be used to vaporize the resin contained within, or an extract of, medical marijuana;
 - (2) Vaporizing devices shall not be capable of being heated to temperatures at which medical marijuana plant material will burn.

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3796:8-2-02 Establishment of additional forms or methods of administration.

- (A) New forms of medical marijuana or methods of administration shall not be purchased by, stored, possessed, offered for sale, or sold by a dispensary unless the form or method has been approved by the state board of pharmacy.
- (B) Persons seeking to add a form or method of administration shall submit a petition in accordance with section 3796.061 of the Revised Code to the state board of pharmacy, which can be accessed by visiting medicalmarijuana.ohio.gov.
- (C) The board shall only consider a petition if it includes all of the following:
- (1) Scientific evidence, capable of being reproduced by multiple scientific experts, supporting the addition of the form or method of administration;
 - (2) An opinion from at least one scientific expert supporting the addition of the form or method of administration. The scientific expert must have specialized knowledge acquired through experience, education or observation, or study that is not possessed by the average layperson;
 - (3) The extent to which the prospective form or method of administration is generally accepted by the medical community;
 - (4) Information or studies known to the petitioner regarding any benefit or adverse effects from the use of the proposed form or method of administration; and
 - (5) Benefits to approving the proposed form or method of administration.
- (D) If a form or method has been previously considered and rejected by the board, or is determined by the board to be substantially similar to a rejected form or method of administration, the board may deny the petition without first considering the appropriateness, unless new scientific research supporting the request is included in the petition.
- (E) In addition to information provided in a petition, the board may examine scientific, medical or other evidence and research pertaining to the petition and may gather information, in person or in writing, from other persons knowledgeable about the form or method of administration ~~being considered~~ [included in the petition](#).
- (F) ~~At least five members of the board, which constitutes a~~ [A](#) quorum [of the board](#), shall consider each proposed form or method of administration. A majority of the board members present at the hearing where each proposed form or method was publicly considered shall concur in the decision to approve or deny the addition of the proposed form or method [included in the petition](#).
- (G) If ~~after consideration~~ the board ~~concludes that the form or method of administration should be added to the list of approved forms and methods~~ [approves a form or method of administration contained within the petition](#), the board shall proceed to adopt a rule, in accordance with Chapter 119. of the Revised Code, ~~expanding the list accordingly~~ [to amend rule 3796:8-2-01 of the Administrative Code](#).

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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;
- (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.

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3796:8-2-04 Quantity of medical marijuana that may be purchased by a patient or caregiver.

(A) A patient and a patient's caregiver(s) may collectively purchase no less than a whole day unit at a single time. A whole day unit shall equal the following amounts for each authorized form of medical marijuana:

(1) ~~One-tenth of an ounce (two and eighty-three hundredths grams) of plant material;~~ Plant material:

~~-(a) Two and fifty-two hundredths grams of tier I medical marijuana;~~

~~-(b) One and sixty-seven hundredths gram of tier II medical marijuana.~~

(2) Two-hundred ninety-five milligrams of THC contained in a patch, lotion, cream, or ointment;

(3) One hundred ten milligrams of THC contained in an oil, tincture, capsule, or edible for oral administration;

(4) Five hundred ninety milligrams of THC contained in oil for vaporization.

(B) A patient and the patient's caregiver(s) may collectively purchase, within a ninety-day period, no more than a ninety-day supply. A ninety-day supply may consist of multiple forms of medical marijuana, but the total ninety-day supply shall not exceed a ninety-day supply whether purchased as a single form or aggregated across forms. A ninety-day supply is defined by form as follows:

(1) Plant material:

(a) No more than eight ounces (two hundred twenty-six and eight-tenths grams) of tier I medical marijuana;

(b) No more than five and three-tenths ounces (one hundred fifty and three-tenths grams) of tier II medical marijuana.

(2) No more than twenty-six and fifty-five-hundredths grams of THC content in patches for transdermal administration or lotions, creams, or ointments for topical administration;

(3) No more than nine and nine-tenths grams of THC content in oil, tincture, capsule, or edible form for oral administration;

(4) No more than fifty-three and one-tenths grams of THC content in medical marijuana oil for vaporization.

(C) Notwithstanding paragraphs (A) and (B) of this rule, a patient who is diagnosed with a terminal illness and the patient's caregiver(s) may collectively purchase, within a ninety-day period, no more than a ninety-day supply. A ninety-day supply may consist of multiple forms of medical marijuana, but the total ninety-day supply shall not exceed a ninety-day supply whether purchased as a single form or aggregated across forms. A ninety-day supply is defined by form as follows:

(1) Plant material:

(a) No more than ten ounces (two hundred eighty-three and five-tenths grams) of tier I medical marijuana;

(b) No more than six and six-tenths ounces (one hundred eighty-seven and one-tenths grams) of tier II medical marijuana.

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- (2) No more than thirty-three and three-tenths grams of THC content in patches for transdermal administration or lotions, creams, or ointments for topical administration;
- (3) No more than eleven and seven-tenths grams of THC content in oil, tincture, capsule, or edible form for oral administration;
- (4) No more than sixty-five and seven-tenths grams of THC content in medical marijuana oil for vaporization.

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3796:8-2-05 Assignment of a product identifier.

- (A) Before any medical marijuana ~~strain or medical marijuana~~ product may be sold to a dispensary, the form for each dose and packaged quantity of that product must be registered with the department pursuant to Chapter 3796:5-8 of the Administrative Code and assigned a product identifier pursuant to this rule.
- (B) Each cultivator with a processor designation and processor that intends to sell medical marijuana to a dispensary shall provide the following information to the state board of pharmacy for each form and dose of each medical marijuana strain and medical marijuana product:
- (1) Name of the medical marijuana entity;
 - (2) Medical marijuana entity license issued by the department;
 - (3) Name of product;
 - (4) Product description, including but not limited to:
 - (a) The form and intended method or methods of administration; and
 - (b) An image of the product;
 - (5) Product dose;
 - (6) Days¹ supply of the product for each product package that will be available;
 - (7) Product ingredients;
 - (8) Proof that the product has been registered with the department pursuant to Chapter 3796:5-8 of the Administrative Code;
 - (9) Remit required fee; and
 - (10) Any additional items deemed necessary by the state board of pharmacy.
- (C) After reviewing the information submitted in accordance with paragraph (B) of this rule, the state board of pharmacy shall determine whether the product complies with ~~the limitations on form in accordance with~~ section 3796.06 of the Revised Code and this division. Issuance of a product identifier shall serve as evidence that the registered product complies with ~~the limitations on form in accordance with~~ section 3796.06 of the Revised Code and this division.

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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 or no more than one hundred-five per cent of the concentration of total target THC, ~~THCA,~~and CBD, ~~or CBDA~~content indicated ~~on the label~~in the product identifier assignment application.

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3796:8-3-01 Product identifier fee.

The non-refundable fee for the assignment of a product identifier is one hundred dollars [plus a service fee](#).

- (A) A single fee shall be remitted for each dose of each medical marijuana strain and medical marijuana product. No further fee is required for the assignment of a product identifier for additional packaged quantities.
- (B) All fees required under this rule shall be paid to the state board of pharmacy by check, or other method approved by the state board of pharmacy, made payable to the “~~Treasurer, State of Ohio~~ [treasurer of state](#).”