



State Medical Board of
Ohio



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Physician Certificate to Recommend Medical Marijuana and Petition for Added Qualifying Condition

Posted: December 15, 2016

Overview

The State Medical Board of Ohio is tasked with developing rules that will regulate the issuance of certificates to physicians wishing to be able to recommend medical marijuana for their patients. The Medical Board is also responsible for establishing the procedure for adding conditions or diseases which may qualify patients for the state's Medical Marijuana Control Program.

The primary focus of the rules is to develop a program that balances access for patients with patient safety. The draft rules presented to the Medical Marijuana Advisory Committee were developed after benchmarking with other states, talking with Ohio physicians and talking with patient advocates. The draft rules closely follow established procedures and standards for obtaining and maintaining an Ohio Medical license.

How can I provide comments?

Written comments will be accepted until **5 p.m. EST on January 13, 2017**.

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

When preparing your comments, be sure to:

- 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

More Information

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

PHYSICIAN CERTIFICATE TO RECOMMEND MEDICAL MARIJUANA

4731-32-01 Definition of terms.

- (A) "Annual report" means the annual compilation of information a physician holding a certificate to recommend medical marijuana must submit to the board that describes the physician's observation regarding the efficacy of treatment with medical marijuana.
- (B) "Board" means the state medical board of Ohio.
- (C) "Caregiver" means an individual registered under Section 3796.08 of the Revised Code to assist a registered patient in the use or administration of medical marijuana.
- (D) "Certificate to recommend medical marijuana" means the certificate issued by the board authorizing a physician to recommend treatment with medical marijuana.
- (E) "Drug database" means the database established and maintained by the board of pharmacy pursuant to section 4729.75 of the Revised Code.
- (F) "Marijuana" means marihuana as defined in section 3719.01 of the Revised Code.
- (G) "Medical marijuana" means marijuana that is cultivated, processed, dispensed, tested, possessed, or used for a medical purpose. Medical marijuana is a schedule II controlled substance pursuant to division (B) of section 3796.01 of the Revised Code.
- (H) "Medical marijuana entity" means a medical marijuana cultivator, processor, or testing laboratory licensed by the department of commerce under section 3796.09 of the Revised Code, or a retail dispensary licensed by the board of pharmacy under section 3796.10 of the Revised Code.
- (I) "Patient" means an individual diagnosed with a qualifying medical condition as defined in division (A) of section 3796.01 of the Revised Code and who is seeking to use medical marijuana.
- (J) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.



4731-32-02 Certificate to Recommend Medical Marijuana

(A) Eligibility for a certificate to recommend medical marijuana requires that all of the following requirements be met:

- (1) The applicant holds an active, unrestricted license to practice medicine and surgery or osteopathic medicine and surgery under section 4731.14 or 4731.29 of the Revised Code;
- (2) The applicant has been granted access to and is not under any prohibition for access to the drug database established and maintained by the board of pharmacy pursuant to section 4729.75 of the Revised Code.
- (3) The applicant holds an active registration with the drug enforcement administration
- (4) The applicant has not been denied a license to prescribe, possess, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, personally furnishing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug.
- (5) The applicant has not held a license issued by the drug enforcement administration or a state licensing administration in any jurisdiction, under which the person may prescribe, personally furnish, dispense, possess, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug.
- (6) The applicant has not been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescriber's inappropriate prescribing, personally furnishing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.
- (7) The applicant has completed at least two hours of continuing medical education in a course or courses certified by the Ohio state

medical association or the Ohio osteopathic association that assist physicians in both of the following:

(a) Diagnosing qualifying medical conditions as defined in Section 3796.01 of the Revised Code;

(b) Treating qualifying medical conditions with medical marijuana, including the characteristics of medical marijuana and possible drug interactions.

(8) The applicant has no ownership or investment interest in or compensation agreement with any medical marijuana entity licensed or applicant seeking licensure under Chapter 3796. of the Revised Code.

(B) An applicant for a certificate to recommend medical marijuana shall file an application under oath with the board in compliance with section 4731.30 of the Revised Code.

(1) An application shall be considered complete when all the following requirements are met:

(a) Evidence of all the requirements in paragraph (A) are received by the board.

(b) The board is not conducting an investigation pursuant to section 4731.22 of the Revised Code of evidence appearing to show that the applicant has violated section 4731.22 or 4731.30 of the Revised Code or applicable rules adopted by the board.

(2) The application shall be processed in accordance with the following:

(a) All application materials submitted to the board will be thoroughly investigated. The board may contact individuals, agencies, or organizations for information about applicants as the board deems necessary. As part of the application process, an applicant may be requested to appear before the board or a board representative to answer questions or provide additional information.

(b) Any applicant to whom the board proposes to deny certificate issuance shall be entitled to a hearing on the issue of such proposed denial in compliance with the provisions of Chapter 119. of the Revised Code and the rules in chapter 4731-13 of the Administrative Code.



- (c) No application for a certificate to recommend medical marijuana may be withdrawn without the approval of the board.
- (3) The following processes apply when an application is not complete within six months of the date the application is received by the board:
- (a) If the application is not complete because required information, facts, or other materials have not been received by the board, the board may notify the applicant that it intends to consider the application abandoned if the application is not completed.
 - (i) The notice shall specifically identify the information, facts, or other materials required to complete the application and inform the applicant that the information, facts, or other materials must be received by the specified deadline date. The notice shall also inform the applicant that if the application remains incomplete at the close of business on the deadline date the application may be deemed to be abandoned.
 - (ii) If all of the information, facts, or other materials are received by the board by the deadline date and the application is determined to be complete, the board shall process the application and may require updated information as it deems necessary.
 - (b) If the application is not complete because the board is investigating, pursuant to section 4731.22 of the Revised Code, evidence appearing to show that the applicant has violated Chapter 4731. of the Revised Code or applicable rules adopted by the board, the board shall do both of the following:
 - (i) Notify the applicant that although otherwise complete, the application will not be processed pending completion of the investigation; and
 - (ii) Upon completion of the investigation and the determination that the applicant is not in violation of statute or rule, process the application, including requiring updated information as it deems necessary.
- (C) The certificate to recommend shall be renewed when the holder's license to practice as a physician or osteopathic physician is renewed or restored,

conditioned upon the holder's certification of having met the requirements in paragraph (A) of this rule.

- (D) The board shall notify the board of pharmacy if a physician's certificate to recommend is lapsed, surrendered, suspended, revoked or otherwise not renewed.

Rule 4731-32-03 Standard of Care

In order to practice within the minimal standards of care when recommending treatment with medical marijuana, a physician shall comply with all of the following requirements:

- (A) The physician shall establish and maintain a bona fide physician-patient relationship with the patient for the provision of medical services that is established in an in-person visit that complies with this rule and for which there is an expectation that the physician will provide care to the patient on an ongoing basis.
- (B) The physician shall create and maintain a medical record that documents the provision of medical services. The documentation shall include all of the following:
 - (1) Patient's name and date or dates of office visits or treatments;
 - (2) A description of the patient's current medical condition;
 - (3) Documented assessment of the patient's medical history, including prescription history and any history of substance use disorder;
 - (4) Documented review of any available relevant diagnostic test results;
 - (5) Documented review of prior treatment and the patient's response to the treatment;
 - (6) Documented review of the patient's current medication to identify possible drug interactions, including benzodiazepines and opioids.
 - (7) Documented review that that standard medical treatment has been attempted or considered, and one of the following is met:
 - (a) The patient had inadequate treatment response to standard medical treatment;
 - (b) The patient was unable to tolerate the standard medical treatment;



- (c) Standard medical approaches are not appropriate in this patient for other documented reasons

- (8) Based on evidence or behavioral indications of addiction or drug abuse, the physician may obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug to be screened.

- (9) The physician's performance of a physical examination relevant to the patient's current medical condition;

- (10) The physician's diagnosis of the patient's medical condition;

- (11) If the patient has been previously diagnosed with a qualifying medical condition as defined in section 3796.01 of the Revised Code, by a physician licensed to practice medicine under section 4731.14 or 4731.29 of the Revised Code, the physician may confirm the diagnosis so long as the physician obtains a copy of medical records or a detailed written summary indicating the diagnosis and the physician is satisfied that he or she can rely on those records to confirm diagnosis of a qualifying condition. The practitioner shall maintain a copy of any record or report of any physician on which the physician relied for purposes of meeting the requirements under this paragraph.

- (C) If the physician diagnoses or confirms the diagnosis of a qualifying medical condition, as that term is defined in section 3796.01 of the Revised Code, the physician shall document in the medical record compliance with all of the following actions when recommending treatment with medical marijuana:
 - (1) Development of a treatment plan, including consideration of whether treatment with medical marijuana is complementary to conventional treatment;

 - (2) The review of the report concerning the patient obtained from the drug database established and maintained by the board of pharmacy pursuant to section 4729.75 of the Revised Code. The report shall cover at least the twelve months immediately preceding the date of the report;

 - (3) Discussion with the patient any indicators of possible abuse or diversion of controlled substances that are reflected on the drug database report obtained from the board of pharmacy;

- (4) The explanation of the risks and benefits of treatment with medical marijuana as it pertains to the patient's qualifying medical condition and medical history and the physician's opinion that the benefits of medical marijuana outweigh the risks.
 - (5) The patient's consent prior to completing a recommendation for treatment with medical marijuana. If the patient is a minor, the physician shall obtain the consent of the patient's parent or legal representative prior to completing a recommendation for treatment with medical marijuana for the patient.
 - (6) Whether the patient needs a caregiver to assist in the use or administration of medical marijuana. If the patient does need a caregiver, the physician shall document the name of the caregiver designated by the patient or the patient's legal representative.
- (D) In recommending treatment with medical marijuana, the physician shall complete all of the following actions:
- (1) Determine from the medical marijuana patient registry established and maintained by the board of pharmacy whether the patient has an active registration for medical marijuana.
 - (a) If patient is not registered, submit the patient's application for registration in compliance with the requirements of section 3796.04 of the Revised Code and the rules of the board of pharmacy adopted under section 3796.06 of the Revised Code.
 - (b) If the patient holds an active registration in the medical marijuana patient registry, the physician shall review the patient's activity
 - (i) If the drug database report indicates that the patient has received a recommendation for treatment with medical marijuana in the immediately preceding twelve months, the previous recommendation must be inactive prior to making a recommendation for the patient's treatment with medical marijuana;
 - (ii) If the drug database report indicates that the patient has received a recommendation for treatment with medical marijuana in the immediately preceding 90 days, no recommendation shall be made.



- (iii) If the drug database report indicates that the patient has not received a recommendation for treatment with medical marijuana in the immediately preceding twelve months, the physician may proceed with issuing the recommendation pursuant to section (D)(2) of this rule
- (2) Prepare the recommendation form in compliance with rules promulgated by the board of pharmacy. The recommendation shall include the following information:
 - (a) The date the recommendation was issued;
 - (b) The physician's name, business address, and telephone number;
 - (c) The physician's license number and certificate to recommend identification issued by the medical board and the registration number from the Drug Enforcement Administration.
 - (d) The patient's name, date of birth, address, qualifying condition and medical marijuana patient registry identification number.
 - (e) The expiration date of the recommendation and number of renewals, if any, not to exceed three 90-day supply renewals.
 - (f) Any instructions for use of medication marijuana, as determined by the physician.
- (E) A physician who recommends treatment with medical marijuana shall be available to provide follow-up care and treatment to the patient, including physical examinations relevant to the patient's condition to determine the efficacy of medical marijuana in treating the patient's qualifying medical condition.
- (F) The physician shall terminate or decline to issue new recommendation for medical marijuana under any of the following circumstances:
 - (1) The physician has determined that the benefits of medical marijuana no longer outweigh the risks.
 - (2) The patient no longer has the diagnosis of or symptoms of the qualifying medical condition.
 - (3) The physician no longer has a valid certificate to recommend medical marijuana.
 - (4) The physician has concerns that the patient or caregiver is abusing or diverting medical marijuana.

(5) The patient is deceased.

Within 5 business days, the physician shall notify the patient and the state board of pharmacy of the termination of the recommendation for medical marijuana or the fact that the physician declined to issue a new recommendation for medical marijuana.

- (G) The records required for recommendation of medical marijuana may be kept with the patient's other medical records and shall be retained for at least three years following the last office visit by the patient.
- (H) The physician shall submit to the board an annual report describing the physician's observations regarding the effectiveness of medical marijuana in treating patients. The report shall not contain patient-identifying information.

4731-32-04 Suspension and Revocation of Certificate to Recommend

- (A) The board may suspend or revoke a certificate to recommend treatment with medical marijuana or impose one or more of the other disciplinary actions authorized by section 4731.22 of the Revised Code for one or more of the applicable reasons in that section. The action shall be a disciplinary matter and shall be conducted in compliance with division (C) of section 4731.22 of the Revised Code and the rules in chapter 4731-13 of the Administrative Code.
- (B) When a certificate to recommend treatment with medical marijuana is suspended it may be reinstated pursuant to conditions stated in the board order or consent agreement that imposed the suspension. The conditions for reinstatement may include, but are not limited to the following:
 - (1) Submission of a written application for reinstatement of the certificate to recommend medical marijuana that meets the requirements of rule 4731-32-02 of the Administrative Code;
 - (2) Payment of all appropriate fees, civil penalties, and fines as provided in Chapter 4731. of the Revised Code;
 - (3) Successful completion of specified additional education or training;
 - (4) Reexamination;
 - (5) Practice limitations;
 - (6) Demonstration that the respondent can resume practice in compliance with acceptable and prevailing standards.



4731-32-05 Petition to Request Additional Qualifying Condition or Disease

- (A) A petition to request the approval of a condition or disease to be designated as a qualifying medical condition shall be submitted to the board in the manner required by the board.
- (B) No later than October 15 of each year, the board shall designate a period during which petitions will be accepted in the next calendar year. Petitions will not be accepted after the expiration of the acceptance period.
- (C) A petition shall include all of the following information:
- (1) The name and contact information for the person submitting the petition.
 - (2) The specific disease or condition requested to be added as a qualifying condition;
 - (3) Information from experts who specialize in the study of the disease or condition;
 - (4) Relevant medical or scientific evidence pertaining to the disease or condition;
 - (5) Evidence that conventional medical therapies are insufficient to treat or alleviate the disease or condition;
 - (6) Evidence supporting the use of medical marijuana to treat or alleviate the disease or condition, including journal articles, peer-reviewed studies, and other types of medical or scientific documentation;
 - (7) Letters of support provided by physicians with knowledge of the disease or condition. This may include a letter provided by the physician treating the petitioner, if applicable.
- (D) The state medical board shall not consider a petition seeking to add a broad category of diseases or conditions.

- (E) In making its decision, the board shall review the petitions and supporting material.
 - (1) The board may consolidate the review of two or more petitions submitted for the same or similar diseases or conditions.
 - (2) The board may establish a limit on the number of petitions to be considered in a calendar year.
 - (3) The board shall consult with one or more experts who specialize in the disease or condition.
 - (4) The board shall review any relevant medical or scientific evidence pertaining to the disease or condition.
 - (5) The board shall consider whether conventional medical therapies are insufficient to treat or alleviate the disease or condition.
 - (6) The board shall review evidence supporting the use of medical marijuana to treat or alleviate the disease or condition.
 - (7) The board shall review any letters of support provided by physicians with knowledge of the disease or condition, including any letter provided by a physician treating the petitioner, if applicable.
 - (8) The board shall review any other relevant evidence regarding the disease or condition.
- (F) The board will issue a written decision no later than 180 days after the acceptance period closes unless the board determines that good cause exists to allow an extension. The board shall notify the petitioner of its decision and publish the decision on the medical marijuana control program website.
- (G) Any petition for a condition that has been previously reviewed by the board and rejected will not be considered by the board unless new scientific research that supports the request is offered.