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Guidelines for the Recommendation of Cannabis for Medical Purposes

MEDICAL BOARD OF CALIFORNIA

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Medical Board of California's Guidelines for the Recommendation of Cannabis for Medical Purposes November 2017

PREAMBLE

The Medical Board of California (Board) developed these guidelines since cannabis is a permissible treatment modality in California under qualifying circumstances. The Board wants to assure physicians who choose to recommend cannabis for medical purposes to their patients, as part of their regular practice of medicine, that they will not be subject to investigation or disciplinary action by the Board if they arrive at the decision to make this recommendation in accordance with accepted standards of medical responsibility. The mere receipt of a complaint that the physician is recommending cannabis for medical purposes will not generate an investigation absent additional information indicating that the physician is not adhering to accepted medical standards.

These guidelines are not intended to mandate the standard of care. The Board recognizes that deviations from these guidelines may occur and may be appropriate depending upon the unique needs of individual patients. Medicine is practiced one patient at a time and each patient has individual needs and vulnerabilities. Physicians should document their rationale for each recommendation decision.

BACKGROUND

On November 5, 1996, the people of California passed Proposition 215. Through this Initiative Measure, Section 11362.5 was added to the Health and Safety Code, and is also known as the Compassionate Use Act of 1996 (Act). The purposes of the Act include, in part:

"To ensure that seriously ill Californians have the right to obtain and use cannabis for medical purposes where the medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of cannabis in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which cannabis provides relief; and

To ensure that patients and their primary caregivers who obtain and use cannabis for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction."

The Act provides that physicians will not be subject to investigation or disciplinary action by the Board if they arrive at the decision to make this recommendation in accordance with accepted standards of medical responsibility.

Although the Act allows the use of cannabis for medical purposes by a patient upon the recommendation of a physician, California physicians should bear in mind that cannabis is listed in Schedule I of the federal Controlled Substances Act. Based on the increasing number of states permitting the recommendation of cannabis in patient care, the U.S. Department of Justice updated its cannabis enforcement policy in August 2013 (James M. Cole, "Guidance Regarding Cannabis Enforcement [Memorandum]," Washington, DC: Department of Justice. (August 19, 2013)). This policy reiterates cannabis's classification as an illegal substance under federal law, but advises states and local governments that authorize cannabis-related conduct to implement strong and effective regulatory and enforcement systems to address any threat state laws could pose to public safety, public health, and other interests. Should these state efforts be insufficient, the federal government may seek to challenge the regulatory structure itself and bring forward individual enforcement actions including criminal prosecutions, focused on those harms. In this context, the United States Department of Justice advised that it likely was not an efficient use of federal resources to focus enforcement efforts on seriously ill individuals, or on their individual caregivers. In doing so, the guidance drew a distinction between the seriously ill and their caregivers, on the one hand, and large-scale, for-profit commercial enterprises, on the other, and advised that the latter continued to be appropriate targets for federal enforcement and prosecution.

GUIDELINES

The Board has adopted the following guidelines for the recommendation of cannabis for medical purposes.

Physician-Patient Relationship: The health and well-being of patients depends upon a collaborative effort between the physician and the patient. The relationship between a patient and a physician is complex and based on the mutual understanding of the shared responsibility for the patient's health care. The physician-patient relationship is fundamental to the provision of acceptable medical care. Therefore, physicians should document that an appropriate physician-patient relationship has been established, prior to providing a recommendation, attestation, or authorization for cannabis to the patient. Consistent with the prevailing standard of care, physicians should not recommend, attest, or otherwise authorize cannabis for themselves or family members.

Pursuant to Business and Professions (B&P) Code section 2525.2, a physician shall not recommend cannabis for medical purposes to a patient, unless the physician is the patient's attending physician. Health and Safety (H&S) Code section 11362.7(a) defines an "attending physician" as a physician who has taken responsibility for an aspect of the medical care, treatment, diagnosis, counseling, or referral of a patient. The physician must also have conducted a medical examination of the patient before recording in the patient's medical record the physician's assessment of whether the patient has a serious medical condition and whether the use of cannabis for medical purposes is appropriate.

Patient Evaluation: A documented medical examination and collection of relevant clinical history commensurate with the presentation of the patient must be obtained before a decision is

made as to whether to recommend cannabis for a medical purpose. The examination must be an appropriate prior examination, and at minimum, should include the patient's history of present illness; social history; past medical and surgical history; alcohol and substance use history; family history with emphasis on addiction, psychotic disorders, or mental illness; documentation of therapies with inadequate response; and diagnosis requiring the cannabis recommendation. At this time, there is a paucity of evidence for the efficacy of cannabis in treating certain medical conditions. Recommending cannabis for any medical conditions, however, is at the professional discretion of the physician acting within the standard of care. The indication, appropriateness, and safety of the recommendation should be evaluated in accordance with standards of practice as they evolve over time.

The initial evaluation for the condition that cannabis is being recommended must meet the standard of care; accepted standards are the same as any reasonable and prudent physician would follow when recommending or approving any other medication.

It is important to note that B&P Code section 2525.3 states that physicians recommending cannabis to a patient for a medical purpose without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. The use of telehealth in compliance with B&P Code section 2290.5, and used in a manner consistent with the standard of care is permissible.

Informed and Shared Decision Making: The decision to recommend cannabis should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the use of cannabis with the patient. (See Decision Tree in [Appendix 1](#)) Patients should be advised of the variability and lack of standardization of cannabis preparations, as well as the issue that it affects individuals differently. Patients should be reminded that cannabis use may result in cognitive changes that affect function, including driving, and that they should not drive, operate heavy machinery, or engage in any hazardous activity while under the influence of cannabis. As with any medication, patients may be charged with driving under the influence of drugs if they drive while impaired by the substance. If the patient is a minor or without decision-making capacity, the physician should ensure that the patient's parent, guardian or surrogate is fully informed of the risks and benefits of cannabis use, is involved in the treatment plan, and consents to the patient's use of cannabis.

Treatment Agreement: Treatment plans with objectives should be established with the patient as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies, both pharmacologic and non-pharmacologic. It also should specify measurable goals and objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function. The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. The treatment plan should also include an "exit strategy" for discontinuing cannabis use in the event tapering or termination of cannabis use becomes necessary.

A physician should document a written treatment plan that includes:

- Advice about other options for managing the terminal or debilitating medical condition (pursuant to the Act conditions include cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which cannabis provides relief).
- Determination that the patient with a terminal or debilitating medical condition may benefit from the recommendation of cannabis.
- Advice about the potential risks of the medical use of cannabis and reminders to safeguard the cannabis, including but not limited to, the following:
 - The variability of quality and concentration of cannabis;
 - The risk of cannabis use disorder;
 - Potential adverse events, such as exacerbation of psychotic disorder, adverse cognitive effects for children and young adults, falls or fractures, and other risks;
 - Risks of using cannabis during pregnancy or breast feeding;
 - The need to safeguard all cannabis and cannabis-infused products from children, pets, or domestic animals; and
 - The reminder that the cannabis is for the patient's use only and the cannabis must not be sold, donated, or otherwise supplied to another individual.
- Additional diagnostic evaluations or other planned treatments.
- A specific duration for the cannabis authorization for a period no longer than twelve months.
- A specific ongoing treatment plan as medically appropriate.

Qualifying Conditions: At this time, there is a lack of evidence for the efficacy of cannabis in treating certain medical conditions. Recommending cannabis for medical purposes is at the professional discretion of the physician. The indication, appropriateness, and safety of the recommendation should be evaluated in accordance with current standards of practice and in compliance with state laws, rules and regulations which specify qualifying conditions for which a patient may qualify for cannabis for medical purposes.

The Compassionate Use Act names certain medical conditions for which cannabis may be useful, although physicians are not limited in their recommendations to those specific conditions (cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, and migraine). In all cases, the physician should base his or her determination on the results of clinical trials, if available, medical literature and reports, or on experience of that physician or other physicians, or on credible patient reports. In all cases, the physician must determine that the risk/benefit ratio of cannabis is as good, or better, than other treatment options that could be used for that individual patient. A patient need not have failed on all standard medications in order for a physician to recommend or approve the use of cannabis for medical purposes.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly assess the patient's response to the use of cannabis and overall health and level of function. This assessment should include any change in the overall medical condition, any change in the physical and psychosocial function, the efficacy of the treatment to the patient, the goals of the treatment, and the progress of those goals. Recommendations should be limited to the time necessary to appropriately monitor the patient. There should be a periodic review documented at least annually or more frequently as warranted.

When a trial of cannabis for medical use is successful and the physician and patient decide to continue the use of cannabis, regular review and monitoring should be undertaken for the duration of treatment. Continuation, modification or termination of cannabis for medical use should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as diversion. A satisfactory response to treatment would be indicated by an increased level of function and/or improved quality of life. The physician should regularly assess the patient's response to the use of cannabis.

Consultation and Referral: A patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment. The physician should seek a consultation with, or refer the patient to, a pain management physician, psychiatrist, psychologist, and/or addiction or mental health specialist, as needed. The physician should determine that cannabis use is not masking symptoms of another condition requiring further assessment and treatment (e.g., substance use disorder, or other psychiatric or medical condition) or that such use will lead to a worsening of the patient's condition.

Medical Records: Proper record keeping and maintenance should support the decision to recommend the use of cannabis for medical purposes. B&P Code section 2266 requires a physician to maintain adequate and accurate medical records. Medical records need to be complete and legible. In addition, each entry should be dated and signed. Any changes, additions, and/or removal to the medical record made at a later date should also be dated and either signed or initialed.

Information that should appear in the medical record includes, but is not limited to the following:

- The patient's medical history, including a review of health risk factors and prior medical records as appropriate;
- Results of the appropriate prior examination, patient evaluation, diagnostic, therapeutic, and laboratory results;
- Other treatments and prescribed medications, including a review of the Controlled Substance Utilization Review and Evaluation System (CURES);
- Authorization, attestation or recommendation for cannabis, to include date, expiration, and any additional information required by state statute;
- Instructions to the patient, including discussions of risks and benefits, side effects and variable effects;
- Results of ongoing assessment and monitoring of patient's response to the use of cannabis;
- A copy of a signed treatment agreement, including instructions on safekeeping and instructions on not sharing cannabis.

Physician Conflicts of Interest: B&P Code section 2525 includes a provision that makes it unlawful for a physician who recommends cannabis for a medical purpose to accept, solicit, or offer any form of remuneration from or to a facility, as defined, if the physician or his or her immediate family have a financial interest in that facility. A violation of this law is a

misdemeanor punishable by up to one year in county jail and a fine of up to five thousand dollars or by civil penalties of up to five thousand dollars and constitutes unprofessional conduct.

“Financial Interest” includes, but is not limited to, any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the licensee refers a person for a good or service. For further information on the full definition of “financial interest” see B&P Code section 650.01.

Additionally, B&P Code section 2525.4 indicates that it is unprofessional conduct for any attending physician recommending cannabis for medical purposes to be employed by, or enter into any other agreement with any person or entity dispensing cannabis for medical purposes.

Accordingly, a physician who recommends cannabis should not have a professional office located at a dispensary or cultivation center or receive financial compensation from or hold a financial interest in a dispensary or cultivation center. Nor should the physician be a director, officer, member, incorporator, agent, employee, or retailer of a dispensary or cultivation center. A cannabis clinic or dispensary may not directly or indirectly employ physicians to provide cannabis recommendations.

Appendix 1: Decision Tree

