

DRAFT
STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY FOR
Proposed Amendments to Rules and Regulations Pertaining to
Medical Use of Marijuana (5 CCR 1006-2), Regulation 3 and 8 – Physician Regulations and
Processes for Verifying a Physician is Eligible to Recommend Medical Marijuana and
Referring Physician to the Board of Medical Examiners
March 16, 2011

Basis and Purpose.

The Colorado Department of Public Health and Environment (department) is the state health agency responsible for the administration of the medical marijuana registry. Pursuant to Article XVIII, Section 14 of the Colorado Constitution, the department must review recommendations from physicians as part of a patient's application for the medical marijuana registry. With the passage of Senate Bill 10-109 and House Bill 10-1284, C.R.S. § 25-1.5-106 was amended to require the department to regulate certain physician activities for purposes of the medical marijuana registry. These proposed rules address four key areas regarding regulations for physicians who recommend medical marijuana:

1. Standards for physician conduct for purposes of the medical marijuana program, including definitions of "in good standing" and "bona fide physician-patient relationship", requiring the maintenance of medical records for medical marijuana patients, and establishing financial prohibitions for physicians who recommend medical marijuana;
2. Setting reasonable cause standards for referrals of physicians by the department to the Colorado Medical Board for potential violations of the Colorado Medical Practice Act;
3. Setting reasonable cause standards for the department to impose sanctions on physicians who recommend medical marijuana for potential violations of financial prohibitions for such physicians; and
4. Establishing appeal rights for physicians against whom the department has proposed a sanction.

These rules specify that a physician making a recommendation for purposes of the medical marijuana registry must have an unrestricted and unconditioned license, have a bona fide physician-patient relationship with a patient for whom the physician diagnoses a debilitating medical condition and recommends the use of medical marijuana, comply with the Colorado Medical Practice Act, C.R.S. § 12-36-101 et seq., and that the physician cannot make physical examinations by remote means. C.R.S. § 25-1.5-106 also allows the department to make referrals to the Colorado Medical Board for enforcement and states that if the department has reasonable cause to believe that a physician has violated Section 14 of Article XVIII of the Colorado Constitution, C.R.S. § 25-1.5-106 or the department rules, then the department may refer the physician to the Colorado Medical Board. These rules lay out the criteria used for any such referrals. The rules also describe certain financial activities that are prohibited for

physicians that recommend medical marijuana, such as offering discounts to patients who agree to use a particular medical marijuana distributor or having a financial interest in a medical marijuana distributor if the physician also recommends marijuana, and provide appeal rights to physicians whom the department proposes to sanction for violations of these financial prohibitions.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:

C.R.S. § 25-1.5-106 and Colorado Constitution article XVIII, section 14.

Major Factual and Policy Issues Encountered.

The department took the proposed rules to the Medical Marijuana Advisory Committee (Committee) for review and comment prior to finalizing the rules for presentation to the Colorado Board of Health. The Committee is comprised of 12 members, who include physicians, law enforcement, a patient, a primary care-giver, and a medical marijuana center operator. This Committee is tasked with conducting public meetings to review all rules prior to submission to the Colorado Board of Health for promulgation.

A major issue discussed and considered by the Committee has to do with the term *restricted* in relation to a physician's license. Of issue is whether or not a *conditioned* license is a type of restricted license for purposes of physician eligibility to recommend medical marijuana for a patient seeking a medical marijuana certificate. While state statute prohibits a physician with a restricted license from making medical marijuana recommendations, the Colorado Medical Board uses the words *restricted* and *conditioned* interchangeably. In other words, the reason for which a physician might be limited to a restricted license could be the same reason for which a physician might be limited to a conditioned license. Similarly, Colorado Medical Board Rule 900(1)(a) defines an "active, unrestricted license" as "a license not currently subject to any practice restrictions, terms, or conditions, including but not limited to terms of probation." Additionally, prior to the passage of legislation during the 2010 legislative session, both *restricted* and *conditioned* had been used to refer to licenses limitations based on a physical condition of the physician and which otherwise would not exclude a physician from recommending marijuana. As the new requirements in the Medical Practice Act allow for a physician with a disability to enter into a confidential agreement with the Colorado Medical Board regarding any practice limitations due to the disability, it was decided that requiring a physician's license be both unrestricted and unconditioned was appropriate.

A second issue considered by the Committee had to do with what makes a bona fide physician-patient relationship. Wording that was targeted at physicians whose practice is predominantly recommending marijuana was dropped. The proposed language was an attempt to preclude medical marijuana mills, and instead require coordination of care between the physician making the medical marijuana recommendation, if that person is not the patient's primary care physician, and the patient's primary care physician. This alternative was rejected as, based on the data currently available, it is too difficult to separate out "mill" physicians from those doctors who provide good medical care, but whose practice involves a higher number of medical marijuana recommendations. This could be due to the type of practice (oncology, for instance) or due to the fact that the doctor may be the only physician in a rural area willing to write

recommendations, and this data is not currently collected by the department. The sense of the Committee was that the wording would limit access to patients whose primary physician would not consider making a medical marijuana recommendation. The rule instead refers back to the Medical Practice Act and requirements for practicing medicine.

One final issue discussed by the Committee concerned when referrals are made to the Colorado Medical Board for physicians suspected of unprofessional conduct and of violating medical marijuana laws and rules. Data regarding the number of medical marijuana recommendations made by the current top 15 recommending physicians was reviewed in an effort to establish a benchmark for referring physicians who are outliers to the Colorado Medical Board. While there was considerable discussion as to what a reasonable benchmark would be, and the Medical Marijuana Advisory Committee members acknowledged the need to make any criteria clear and non-subjective, it was not clear what numerical cap or percent would best be used as a standard above which referrals would be initiated. The Colorado Medical Board and the Colorado Medical Society participated in the discussion with department staff and Medical Marijuana Advisory Committee members. The Committee voted not to include specific benchmarks in these rules, but rather to leave the determination of such referrals to the department's discretion.

Alternative Rules Considered and Why Rejected.

The department presented the initial proposed rules to the Committee for comment in three public meetings as described above. The current rules reflect changes approved by a majority of the Committee.

One alternative rule would have removed the word *unconditioned* from the rule. However, with at least one of the Colorado Medical Board rules defining an unrestricted license as a license without conditions, a change in Colorado Medical Board procedures to allow physicians with restricted or conditioned licenses based upon a disability to hold an active license and enter into a confidential agreement with the Colorado Medical Board concerning any practice limitations, and the acknowledgement that some conditions do reflect substance abuse, a majority of Committee members voted to leave the term *unconditioned* in the rule.

Another alternative rule would have required physicians who recommend medical marijuana to see these patients for more than just medical marijuana recommendations. The Committee ultimately rejected this proposal as there was concern that some physicians are not comfortable making medical marijuana recommendations; thus, requiring a recommending physician to be essentially the patient's primary care physician was perceived as limiting patient choice.

Finally, the Committee considered and rejected rule language regarding referrals to the Colorado Medical Board by the department when the physician saw more patients for purposes of the medical marijuana program than was thought to be reasonably possible in a given timeframe. The draft language was written broadly to allow for a variety of fact scenarios to result in a potential referral; however, the Committee initially preferred to set a specific numeric standard, but then ultimately determined that deferral to the department's discretion to make referrals, due to the myriad number of potential fact patterns that defy a singular standard, was preferable. The wording was removed and the department retains discretion as to when a referral to the Colorado Medical Board would be appropriate.

STATE OF COLORADO

Bill Ritter, Jr., Governor
Martha E. Rudolph, Executive Director

Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

NOTICE OF PUBLIC RULE-MAKING HEARING BEFORE THE COLORADO BOARD OF HEALTH

NOTICE is hereby given pursuant to the provisions of Section 24-4-103, C.R.S., that the Colorado Board of Health will conduct a public rule-making hearing on **March 16, 2011** in the Sabin-Cleere Conference Room of the Colorado Department of Public Health and Environment, Bldg. A, First Floor, 4300 Cherry Creek Drive, South, Denver, CO 80246, to consider the promulgation of amendments to 5 CCR 1006-2, **Rules Pertaining to Medical Use of Marijuana-concerning the regulation of physicians for purposes of the medical marijuana registry**. The Board meeting commences in the morning. For the specific time this hearing is scheduled, please consult the meeting agenda on the Board's Web site at <http://www.cdphe.state.co.us/op/bh/index.html> on or after Friday, March 4, 2011, or call (303) 692-3464.

The purpose of this hearing is to receive public comment on proposed amendments to implement the provisions of Article XVIII, section 14 of the Colorado Constitution, H.B. 10-1284 and S.B. 10-109 and to make any necessary conforming amendments. Specifically, the proposed rules establish standards for physician conduct for purposes of the medical marijuana registry program, including adding definitions of "in good standing" and "bona fide physician-patient relationship", requiring maintenance of medical records for medical marijuana patients and establishing financial prohibitions for physicians who recommend medical marijuana. Furthermore, the proposed amendments set reasonable cause standards for referrals of physicians by the department to the Colorado Medical Board for potential violations of the Colorado Medical Practice Act and for the department to impose sanctions on physicians who recommend medical marijuana for potential violations of financial prohibitions for such physicians. The proposed amendments establish appeal rights for physicians against whom the department has proposed a sanction.

The proposed rules have been developed by the Colorado Department of Public Health and Environment pursuant to Section 25-1.5-106, C.R.S.

The notice, proposed rules, statement of basis and purpose, specific statutory authority and regulatory analysis will be available on the Board's Web site at <http://www.cdphe.state.co.us/op/bh/index.html> under "Notices of Upcoming Public Rulemaking Hearings and Draft Proposed Rules" and by calling 303-692-3464.

Public Participation Through Written Comments Encouraged: The Board **STRONGLY** encourages all interested persons and organizations to provide written data, views or comments regarding the proposed rules prior to the hearing. **Written comments shall be submitted by Friday, February 25, 2011 at 5:00 p.m. to:**

Colorado Board of Health
c/o Jamie Thornton, Program Assistant
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South EDO-A5,
Denver, CO 80246-1530,
FAX: 303-691-7702; or
E-mail: cdphe.edobohcomments_physicianregulation@state.co.us

Oral Comment and Testimony May Be Limited. The Board requires the following:

1) Recognized organizations or entities that submit written comments as described above may fax a request for a time allocation to address the Board regarding the proposed rule, not to exceed 10 minutes, to the Board of Health Administrator at 303-691-7702 **by 5:00 p.m., Friday, February 25, 2011**. The request must include the name of the organization, entity or person requesting a time allocation, a contact person, contact person's mailing address, phone number, fax number and email

address, if available, and the amount of time requested. **The recognized organization or entity MUST submit written comments and its request for a time allocation by the February 25, 2011 deadline to receive a time allocation.** The Administrator will notify the requestor of the amount of time allocated on or before Friday, March 4, 2011;

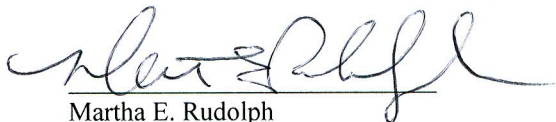
2) Recognized organizations or entities that do not submit written comments by February 25, 2011, will be limited to the time restrictions described in paragraph 4;

3) Individuals that share the same perspective or position regarding the proposed rule that are not representatives of a recognized organization or entity are encouraged to identify one spokesperson to testify at the hearing; and

4) At the discretion of the Hearing Chair, persons or groups choosing not to request a time allocation as outlined in 1 above, may be limited. The time allocated for each such person or group to comment on the proposal will be based on the number of persons wishing to comment and the time allocated for the hearing. Additionally, the Chair shall limit duplicative or repetitive testimony. **All comments will be limited to the subject matter and scope of the proposed amendments.**

The proposed revisions to be considered at the hearing, together with the proposed statement of basis and purpose, specific statutory authority and regulatory analysis will be available for inspection at the above address by any person at least five working days prior to the hearing.

Dated this 28 day of January 2011.

A handwritten signature in black ink, appearing to read 'Martha E. Rudolph', written over a horizontal line.

Martha E. Rudolph
Acting Executive Director

NOTICE OF PUBLIC RULE-MAKING HEARING BEFORE THE COLORADO BOARD OF HEALTH to consider amendments to **5 CCR 1006-2, Rules Pertaining to Medical Use of Marijuana-concerning the regulation of physicians for purposes of the medical marijuana registry.** DATE: March 16, 2011 PLACE: Sabin-Cleere Conference Room, Colorado Department of Public Health and Environment ("CDPHE"), Bldg. A, First Floor, 4300 Cherry Creek Drive, South, Denver, CO 80246. TIME: For the specific time of hearing, consult the meeting agenda on the Board's Web site at <http://www.cdphe.state.co.us/op/bh/index.html> on or after Friday, March 4, 2011. The purpose of the hearing is to receive public comment on proposed amendments to implement the provisions of Article XVIII, section 14 of the Colorado Constitution, H.B. 10-1284 and S.B. 10-109 and to make any necessary conforming amendments. Specifically, the proposed rules establish standards for physician conduct for purposes of the medical marijuana registry program, including adding definitions of "in good standing" and "bona fide physician-patient relationship", requiring maintenance of medical records for medical marijuana patients and establishing financial prohibitions for physicians who recommend medical marijuana. Furthermore, the proposed amendments set reasonable cause standards for referrals of physicians by CDPHE to the Colorado Medical Board for potential violations of the Colorado Medical Practice Act and for CDPHE to impose sanctions on physicians who recommend medical marijuana for potential violations of financial prohibitions for such physicians. The proposed amendments establish appeal rights for physicians against whom CDPHE has proposed a sanction. CDPHE has developed the proposed rules pursuant to C.R.S. 25-1.5-106. **Contact for more information and/or copies of the proposed rules:** The notice, proposed rules, statement of basis and purpose, specific statutory authority and regulatory analysis will be available on the Board's Web site at <http://www.cdphe.state.co.us/op/bh/index.html> under "Notices of Upcoming Public Rulemaking Hearings and Draft Proposed Rules" and by calling 303-692-3464. **Public Participation Through Written Comments Encouraged:** The Board STRONGLY encourages all interested persons and organizations to provide written data, views or comments regarding the proposed rules prior to the hearing. **Written comments shall be submitted by Friday, February 25, 2011 at 5:00 p.m. to:** Colorado Board of Health, c/o Jamie Thornton, Program Assistant, CDPHE, 4300 Cherry Creek Drive South EDO-A5, Denver, CO 80246-1530, FAX: 303-691-7702; or E-mail: cdphe.edobohcomments_physicianregulation@state.co.us **Oral Comment and Testimony May Be Limited. Board requires the following:** 1) Recognized organizations or entities that submit written comments as described above may fax a request for a time allocation to address the Board regarding the proposed rule, not to exceed 10 minutes, to the Board of Health Administrator at 303-691-7702 **by 5:00 p.m., Friday, February 25, 2011.** The request must include the name of the organization, entity or person requesting a time allocation, a contact person, contact person's mailing address, phone number, fax number and email address, if available, and the amount of time requested. **The recognized organization or entity MUST submit written comments and its request for a time allocation by the February 25, 2011 deadline to receive a time allocation.** The Administrator will notify the requestor of the amount of time allocated on or before Friday, March 4, 2011; 2) Recognized organizations or entities that do not submit written comments by February 25, 2011, will be limited to the time restrictions described in paragraph 4; 3) Individuals that share the same perspective or position regarding the proposed rule that are not representatives of a recognized organization or entity are encouraged to identify one spokesperson to testify at the hearing; and 4) At the discretion of the Hearing Chair, persons or groups choosing not to request a time allocation as outlined in 1 above, may be limited. The time allocated for each such person or group to comment on the proposal will be based on the number of persons wishing to comment and the time allocated for the hearing. Additionally, the Chair shall limit duplicative or repetitive testimony. **All comments will be limited to the subject matter and scope of the proposed amendments.**