COLORADO
Department of Public Health & Environment

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To: Members of the State Board of Health

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Date: July 15, 2015

Subject: **Rulemaking Hearing**
Proposed Amendments to 5 CCR 1006-2, Medical Use of Marijuana

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The Medical Marijuana Registry (MMR) is proposing modifications to the Medical Use of Marijuana regulations. The proposed modifications include: remove unnecessary notary requirements; add post-traumatic stress disorder (PTSD) as a new debilitating medical condition, and; address issues brought to the department's attention by the Office of Legislative Legal Services (OLLS) after review of regulation changes approved by the Board of Health in September 2014. Two technical clarifications to correctly identify a paragraph number and correctly reference the State Administrative Procedure Act are included as part of the Regulation 2 proposed changes.

Notice of this rulemaking hearing was sent to stakeholders including: Medical Marijuana Registry stakeholder lists (physicians, caregivers, centers, and "general"), Scientific Advisory Council of the Medical Marijuana Research Grant Program, Colorado Medical Society, Colorado Psychiatric Society, Colorado Academy of Family Physicians, and the petitioner. Details of significant stakeholder comments are included under the relevant proposed regulation modifications below.

A. MODIFICATIONS TO REGULATION 2: APPLICATION FOR A REGISTRY IDENTIFICATION CARD AND REGULATION 4: CHANGE IN APPLICANT INFORMATION

1. Removing the requirement to have a Notary in Regulation 2 and Regulation 4

Board of Health Regulation 2 and Regulation 4 currently include a notary requirement. This requirement was first initiated as a result of a noted trend of caregivers submitting patient change forms without the patient's knowledge or consent. The Medical Marijuana Registry patient verification procedures approved by the Board in September 2014 ensure changes to the patient's record are patient driven. With these adjustments, it is no longer necessary for patients to notarize their application. Removing the notarization requirement reduces the burden on applicants to find and pay for a notary.

2. Minor Technical Cleanup of Regulation 2

The Medical Marijuana Registry proposed to conduct minor cleanup of Regulation 2 part B.5. and part I.2. These two technical clarifications identify a paragraph number by Arabic numeral rather than Roman numeral and correctly reference the State Administrative Procedure Act.

B. MODIFICATIONS TO REGULATION 6: DEBILITATING MEDICAL CONDITIONS AND THE PROCESS FOR ADDING NEW DEBILITATING MEDICAL CONDITIONS

1. Adding PTSD as New Debilitating Medical Condition

On January 27, 2015, the department received a petition from a patient to add PTSD to the list of debilitating conditions for which an individual may apply for participation in the Medical Marijuana Registry. The department reviewed the information submitted in support of the petition and conducted a search of the medical literature for peer-reviewed published randomized controlled trials or well-designed observational studies concerning the use of marijuana for PTSD. This information was presented to the Medical Marijuana Scientific Advisory Council (SAC) on April 10, 2015. Based on the following considerations, the SAC recommended that the department request the Board of Health to add PTSD as a new debilitating condition:

- There is evidence based on one small, well designed, randomized controlled trial that a synthetic cannabinoid (nabilone) similar to THC (primary cannabinoid in marijuana) is effective in treating PTSD nightmares and possibly other PTSD symptoms. There are several supportive lower quality studies also involving either nabilone or THC.

- Disrupted sleep (nightmares and insomnia) is a core component of PTSD associated with significant distress, functional impairment and poor health; it is linked to PTSD development and maintenance. Current PTSD treatments are quite limited in their ability to manage PTSD-related sleep disturbance.

- Existing treatments for PTSD (pharmacotherapy and psychotherapy) have limitations, do not necessarily result in adequate responses in most of those treated, may not be acceptable to some patients, and may not be available everywhere. In addition, many of the supporting studies of treatment efficacy were conducted among a subset of persons with PTSD who may not be representative of all persons with PTSD.

- There are only two FDA-approved drugs for treating PTSD; a number of other recommended drugs are used off-label. This highlights how accepted conventional treatments are not all subject to the same rigorous process of review and approval.

- Although persons with PTSD have access to recreational marijuana in this state, such access is not statewide, and there may be preferred products available only through medical marijuana centers. The network of caregivers also helps address gaps in access to medical marijuana.

- Some persons with PTSD may be receiving medical marijuana cards by selecting a different debilitating condition (e.g., pain) in their application to the Medical Marijuana Registry (MMR). Adding PTSD provides the MMR an opportunity to obtain more accurate information from applicants, and will improve the department's understanding of MMR patients' medical marijuana needs.

- Although marijuana is not without some adverse effects, this is also true of essentially all FDA-approved drugs, including narcotic pain medications which have substantial abuse potential including the risk of lethal overdosing.

The department proposes that the addition of PTSD as a new debilitating condition be limited to a period of four years. At that point, any new evidence of benefit and harm would be reassessed based on additional published results from further clinical trials and well-designed observational studies, such as those approved for funding by the Board of Health as part of the Medical Marijuana Research Grant Program.

Several concerns have been communicated in writing to either CDPHE or the Board regarding this proposal from two members of the SAC. These concerns, followed by the Department's comments, include:

a) "... there are inherent dangers related to cannabis use and PTSD, with recent literature noting worse outcomes ..."

CDPHE Comments:
Although potentially concerning, the literature referenced is not a peer-reviewed journal publication, but rather an abstract of a talk presented in December 2014 at the annual meeting of the American Academy of Addiction and Psychiatry. The paper has not yet been published and thus the methods and findings have not yet been publicly available for review and critique. The Department sought feedback from an expert VA researcher on PTSD who has seen the paper pre-publication. Aspects that influence the paper's reliability include: the study being a secondary data analysis of administrative data, the study being non-generalizeable because the study population consisted of veterans entering intensive residential treatment - which is a very small subset of veterans with PTSD, the study being non-generalizeable to all veterans with PTSD because approximately 74% of veterans nationally do not receive their health care in the VA system (source: FY14 data - Dept. of Veterans Affairs) and the study being non-generalizeable to civilians with PTSD. Based upon the paper being in pre-publication and our preliminary assessment, the Department does not recommend that the Board of Health rely upon the study at this time.

b) "... psychiatrists are highly unlikely to make recommendations for marijuana use in PTSD patients. Consequently, physicians with no psychiatric training will be making these recommendations, practicing outside their scope of expertise ..."

CDPHE Comments:
It is a requirement of the MMR that a physician certify a debilitating medical condition. Physicians other than psychiatrists often manage the more routine mental health conditions and might make recommendations for medical marijuana for PTSD. Primary care physicians receive training and diagnose and treat some psychiatric conditions such as clinical depression on a routine basis. Standard recommended treatment modalities for PTSD include drug therapy and psychotherapy. The only two FDA-approved drugs for PTSD, sertraline and paroxetine, are commonly prescribed for depression and likely very familiar to many primary care physicians. Recently published (December 2013) guidance in the medical journal, American Family Physician (source: www.aafp.org/afp/2013/1215/p827.html) evidences the appropriateness and support for primary care providers diagnosing and initially managing (and referring as necessary) persons with PTSD.

c) "..... It may become a malpractice concern if something goes awry (psychosis, etc). I would ask that you get input from COPIC on this."

CDPHE Comments:

The Department contacted COPIC, a Colorado provider of medical professional liability insurance, and spoke with staff involved in policy underwriting and policyholder service. COPIC supports the clinical decision of physicians to certify appropriate patients for use of medical marijuana. In order to assure safe clinical practice and reduce the risk of liability, COPIC asks questions on the application for malpractice insurance regarding the number and percentage of patients for whom the physician recommends medical marijuana; and questions about having a physician-patient relationship, completing full medical assessments, providing follow-up care, and maintaining appropriate documentation. COPIC has never been involved with a liability claim related to adverse effects or clinical outcomes from use of medical marijuana.

d) "There have already been three deaths in this state related to marijuana users becoming psychotic and engaging in violent behavior. My concern is that veterans with PTSD and co morbid traumatic brain injuries will be particularly vulnerable to the psychoactive properties of cannabis, and at risk for perpetrating violence toward self and others given their greater access to weapons relative to the general population."

CDPHE Comments:

The 3 deaths related to marijuana use were tragic. One concerned a Colorado resident and two involved individuals visiting Colorado. The Department recognizes that there are some risks to medical marijuana treatment. The most concerning risks, however, need to be placed in proper perspective, for example, by comparing them to the risks associated with the use of prescription drugs and prescription drug abuse. The Department is aware of only one of the estimated 500,000 Colorado adult residents who used marijuana ("one or more days in the past month") during 2014 (source: BRFSS, Health Surveys and Analysis Program, CDPHE) engaging in violent behavior resulting in death (of the spouse in this case). Many veterans anecdotally use marijuana without reported incidents of related violence in Colorado. In contrast, during 2014, there were approximately 330 deaths in Colorado due to prescription drug abuse of opioid analgesics (source: Health Statistics Section, CDPHE).

2. Deleting Role of Medical Marijuana Scientific Advisory Council (SAC) in Reviewing Petitions

The rules adopted by the Board of Health in September 2014 authorized the SAC to review and make recommendations concerning petitions to add debilitating conditions. The General Assembly has reviewed the rule and determined that the SAC is not authorized to perform this task. SB 15-100 modifies Regulation 6 to remove the SAC from the petition process. The repeal results in a dangling cross-reference and disjointed language that may confuse stakeholders. The revisions clarify the rule following the feedback by the OLLS and decision of the General Assembly. Though the SAC cannot be utilized in its official capacity, the Department recognizes the expertise of the individual members and may continue outreach to those individuals and other MMR stakeholders that can assist the Department in reviewing petitions to add debilitating conditions.

C. MODIFICATIONS TO REGULATION 14: COLORADO MEDICAL RESEARCH GRANT PROGRAM

The Board of Health approved the addition of Regulation 14 in September 2014, which specifies the administration of the Medical Marijuana Research Grant Program by the department, as authorized by § 25-1.5-106.5, C.R.S. The rule authorized the department to establish timelines. Upon review by the OLLS, part A.2 was determined to be overbroad. SB 15-100 modifies Regulation 14 to remove part A.2. The rule revision replaces part A.2 with

language that is more specific but allows for some flexibility to meet the needs of the grant program and prospective applicants. The revision also adds language regarding the duties of the SAC (with the exception of reviewing petitions to add debilitating conditions) that was previously in Regulation 6, but removed in response to the passage of SB 15-100 (see above).

The portions of the packet highlighted in yellow reflect changes to the rulemaking packet since it was presented to the Board of Health in May. The changes recognize feedback received from stakeholders, incorporate suggestions from the Office of the Attorney General, remove the notary requirement for minors as recommended by Board member Nadeen Ibrahim at the May Board of Health meeting, and respond to the Board of Health's request for additional information concerning the Scientific Advisory Council's discussion of PTSD and in particular, the concerns voiced by SAC members.