



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

To: Members of the State Board of Health

From: Natalie Riggins, Medical Marijuana Program Manager, Center for Health and Environmental Data (CHED); and Ken Gershman, MD, MPH, Manager, Medical Marijuana Research Grant Program, Disease Control and Environmental Epidemiology Division (DCEED)

Through: Dana Erpelding, Director, CHED<sup>DE</sup> and Rachel Herlihy, MD, MPH, Director, DCEED<sup>RE</sup>

Date: May 15, 2015

Subject: Request for Rulemaking Hearing  
Proposed Amendments to 5 CCR 1006-2, Medical Use of Marijuana, with a request for the rulemaking hearing to occur in July of 2015

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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.

#### **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.

## 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.

STATEMENT OF BASIS AND PURPOSE  
AND SPECIFIC STATUTORY AUTHORITY  
for Amendments to  
5 CCR 1006-2, Medical Use of Marijuana

**Basis and Purpose.**

Board of Health Regulation 2 and Regulation 4 require patients to notarize their application and change of patient information forms. 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 or change forms. The changes to Regulation 2 and Regulation 4 remove the notarization requirement.

In addition, the Medical Marijuana Registry proposes 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.

On January 27, 2015, the department received a petition from a patient to add post-traumatic stress disorder (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. Based upon the current process delineated in Board of Health rules, this information was presented to the Medical Marijuana Scientific Advisory Council (SAC) on April 10, 2015. The SAC recommended that the department request a Board of Health rulemaking hearing to add PTSD as a new debilitating condition.

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; this change is effective May 15, 2015. 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.

The Board of Health approved the addition of Regulation 14 in September 2014. Regulation 14 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.; this change is effective May 15, 2015. 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.

**Specific Statutory Authority.**

These rules are promulgated pursuant to the following statutes:  
Colorado Constitution, Article XVIII, Section 14  
§ 25-1.5-106, C.R.S. and § 25-1.5-106.5, C.R.S.

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SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

Yes in part, the bill number is \_SB15-100\_; rules are  authorized  
 required.  
 No

Is this rulemaking due to a federal statutory or regulatory change?

Yes  
 No

Does this rule incorporate materials by reference?

Yes  
 No

Does this rule create or modify fines or fees?

Yes  
 No

REGULATORY ANALYSIS  
for Amendments to  
5 CCR 1006-2, Medical Use of Marijuana

1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Removing the notary requirements

Medical marijuana patients and caregivers will benefit as they will no longer be required to spend time seeking the services of a notary public and will save the \$5 notary fee currently required on the patient application form, patient change of record form, and the caregiver acknowledgement form. These changes provide clarity, and simplify the processes for Medical Marijuana patients and caregivers

Minor Technical Cleanup of Regulation 2

These clarifications may assist medical marijuana registry stakeholders when reviewing the rules.

Adding PTSD as New Debilitating Medical Condition

Individuals with a diagnosis of post-traumatic stress disorder (PTSD) and for whom a physician has recommended the medical use of marijuana would be able to apply for participation in the Medical Marijuana Registry.

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

None. Though the SAC cannot be used in its official capacity, the Department may still ask stakeholders for feedback when reviewing a petition to add a debilitating condition. Members of the SAC may be asked to participate in the petition review process in their individual capacity.

Colorado Medical Research Grant Program - Procedures and Timelines

Applicants responding to requests for applications to the Medical Marijuana Research Grant Program will benefit by being provided more specific timeline information.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Removing the notary requirements

Medical Marijuana applicants and patients will no longer incur the burden or cost (approximately \$5.00) of obtaining a notary.

Minor Technical Cleanup of Regulation 2

These clarifications may assist medical marijuana registry stakeholders when reviewing the rules.

Adding PTSD as New Debilitating Medical Condition

This proposed rule expands the list of eligible conditions for which an individual can apply for participation in the Medical Marijuana Registry. Thus, the number of applicants may increase as a result of this rule, although by how much is difficult to predict. The application process would be identical for an individual with PTSD as for an individual with any of the other qualifying debilitating medical conditions.

Deleting Role of Medical Marijuana Scientific Advisory Council in Reviewing Petitions

None expected as the department may still seek stakeholder feedback to review petitions and provide input to the Department.

Colorado Medical Research Grant Program - Procedures and Timelines

None as the specific dates and requirements are part of the grant application process.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Removing the notary requirements

There is a nominal one-time cost to update forms, websites and related MMR resources.

Minor Technical Cleanup of Regulation 2

None

Adding PTSD as New Debilitating Medical Condition

The Medical Marijuana Registry may see an increase in applications with the expansion of the number of qualifying debilitating medical conditions. The Medical Marijuana Registry has no way to estimate how many new applications may be received based upon this change, but anticipates that the application fees will be sufficient to cover the costs of the increased numbers of applications. There is a nominal one-time cost to update forms, websites and related MMR resources.

Deleting Role of Medical Marijuana Scientific Advisory Council in Reviewing Petitions

None

Colorado Medical Research Grant Program - Procedures and Timelines

None

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Removing the notary requirements

These changes provide clarity and simplify the application and renewal processes for Medical Marijuana patients and caregivers, and will save applicants and caregivers the \$5 notary fee for each form (application, change of patient record and caregiver acknowledgement) submitted. In addition, a notary signature cannot be captured in the new electronic registry system that is currently under development. Once implemented, the new electronic system will save patients, physicians and caregivers time and postage as applications will be submitted electronically, not via the mail.

Minor Technical Cleanup of Regulation 2

The proposed rule modification is necessary to provide clarity and consistency of language and format in Regulation 2.

Adding PTSD as New Debilitating Medical Condition

Article XVIII, Section 14 of the Colorado Constitution requires the state health agency responsible for administration of the Medical Marijuana Registry to accept petitions from patients and physicians to add debilitating medical conditions to the list of qualifying debilitating medical conditions for the program, and either approve or deny such petitions within 180 days of receipt, and to set a rulemaking hearing if the state



health agency deems such hearing to be appropriate. Inaction is not an option as the petition process is delineated in the constitution and statute.

Deleting Role of Medical Marijuana Scientific Advisory Council in Reviewing Petitions

The proposed rule modification is necessary to address the issue raised by OLLS in their review of Regulation 6.

Colorado Medical Research Grant Program - Procedures and Timelines

The proposed rule modification is necessary to address the issue raised by OLLS in their review of Regulation 14.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Removing the notary requirements

No. These changes are the least costly and intrusive, as the proposed rule modification simplifies the application and renewal processes, removing the current notary cost and burden to patients and caregivers.

Minor Technical Cleanup of Regulation 2

No. The proposed rule modification is necessary to provide clarity and consistency of language and format in Regulation 2.

Adding PTSD as New Debilitating Medical Condition

Article XVIII, Section 14 of the Colorado Constitution requires the state health agency responsible for administration of the Medical Marijuana Registry to accept petitions from patients and physicians to add debilitating medical conditions to the list of qualifying debilitating medical conditions for the program, and either approve or deny such petitions within 180 days of receipt, and to set a rulemaking hearing if the state health agency deems such hearing to be appropriate. § 25-1.5-106, C.R.S. authorizes the department to administer the Medical Marijuana Registry program and promulgate rules of administration in conformance with state law. The proposed rules add PTSD to the current Medical Marijuana Registry program rules that list all other qualifying debilitating medical conditions.

Deleting Role of Medical Marijuana Scientific Advisory Council in Reviewing Petitions

No. The proposed rule modification is necessary to address the issue raised by OLLS in their review of Regulation 6.

Colorado Medical Research Grant Program - Procedures and Timelines

No. The proposed rule modification is necessary to address the issue raised by OLLS in their review of Regulation 14.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

Removing the notary requirements

No alternatives to rulemaking were considered as the proposed rule change will simplify the application and renewal processes and reduce cost and burden for Medical Marijuana patients and caregivers.

Minor Technical Cleanup of Regulation 2

No alternatives to rulemaking were considered as the proposed rule modification is necessary to provide clarity and consistency of language and format in Regulation 2.



#### Adding PTSD as New Debilitating Medical Condition

As described above, the rule modification proposed amends the current rule, which lists the qualifying debilitating medical conditions, to add PTSD. Without a rulemaking, the department is unable to amend the list. These rules are authorized by § 25-1.5-106, C.R.S.

#### Deleting Role of Medical Marijuana Scientific Advisory Council in Reviewing Petitions

There are no alternatives to address the issue raised by OLLS in their review of Regulation 6.

#### Colorado Medical Research Grant Program - Procedures and Timelines

There are no alternatives to address the issue raised by OLLS in their review of Regulation 14.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

#### Removing the notary requirements

The Department contacted notaries to assess the approximate current cost of \$5.00. The requirement of a notary does incur a cost of approximately \$5.00, that may be burdensome for some Medical Marijuana patients. This new process allows MMR to verify that the patient is aware of all forms submitted in their name, while eliminating the burden of needing a notary.

#### Adding PTSD as New Debilitating Medical Condition

There is one small randomized, placebo controlled, cross-over design study of the clinical efficacy of a synthetic analogue (nabilone) of delta-9 tetrahydrocannabinol (THC - the major cannabinoid in marijuana) in male military personnel with PTSD and treatment-resistant nightmares. Administration of this synthetic THC was well tolerated and effective in reducing PTSD-related nightmares, as well as self-reported PTSD global improvement, but not in improving sleep quality and quantity. The citation for this study is: Jetly R et al, Psychoneuroendocrinology 2015; 51:585-588. There are two less rigorously designed, open-label (i.e., no placebo control) clinical studies of efficacy of either oral THC or the synthetic THC analogue, nabilone, that reported supportive results. The oral THC administration was well tolerated and effective in improving global PTSD symptoms, nightmares and sleep quality. The nabilone administration was generally well tolerated and resulted in lessening of severity or total cessation of treatment-resistant nightmares. The citations for these two studies, respectively, are: Roitman P, et al, Clinical Drug Investigation 2014;34:587-591; and: Fraser G, CNS Neuroscience & Therapeutics 2009;15:84-88.

Materials that were reviewed by the Department and the Scientific Advisory Council are available as part of the Scientific Advisory Council April 10, 2015 [meeting materials](#).

STAKEHOLDER COMMENTS  
for Amendments to  
5 CCR 1006-2, Medical Use of Marijuana

The following individuals and/or entities were included in the development of these proposed rules: (Please be specific. Identify your stakeholders with enough specificity the Board has context for the extent of the outreach.)

The Medical Marijuana Scientific Advisory Council

The following individuals and or/entities were notified that this rule-making was proposed for consideration by the Board of Health:

The Medical Marijuana Scientific Advisory Council  
Medical Marijuana Registry Stakeholders Lists  
Department of Revenue  
Colorado Medical Society  
Colorado Psychiatric Society  
Colorado Academy of Family Physicians

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

Adding PTSD as New Debilitating Medical Condition

We have received feedback from one physician member of the Medical Marijuana Scientific Advisory Council (SAC) opposing the majority recommendation of the SAC. We anticipate receiving more such comments from the medical community and will update the Board prior to and as part of any rulemaking hearing.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

Removing the Notary Requirement

This proposal removes the requirement for a Notary on the Medical Marijuana application resulting in a cost savings for all applicants; however, homebound patients and applicants eligible for the indigence fee waiver may benefit more.

Minor Technical Cleanup

The proposed rule modification is necessary to provide clarity and consistency of language and format in Regulation 2.

Adding PTSD as New Debilitating Medical Condition

This proposal serves to establish more equitable access to medical marijuana to both veterans and civilians suffering from PTSD, compared with other groups of Coloradoans with debilitating conditions that are already part of the Medical Marijuana Registry. Persons with PTSD who may currently be self-medicating with recreational marijuana may benefit from easier and more affordable access to marijuana through medical marijuana dispensaries.

## DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

## Health and Environmental Information and Statistics Division

## MEDICAL USE OF MARIJUANA

## 5 CCR 1006-2

1 \*\*\*\*\*

2 **Regulation 2: Application for a registry identification card**

3 A. In order to be placed in the registry and to receive a registry identification card, an adult applicant  
4 must reside in Colorado and complete an application form supplied by the department, and have  
5 such application notarized and signed and include the fee payment. The adult applicant must  
6 provide the following information with the application:

7 \*\*\*\*\*

8 B. In order for a minor applicant to be placed in the registry and to receive a registry identification  
9 card, the minor applicant must reside in Colorado and a parent residing in Colorado must consent  
10 in writing to serve as the minor applicant's primary care-giver. Such parent must complete an  
11 application form supplied by the department, and have such application notarized, signed and  
12 include fee payment. The parent of the minor applicant must provide the following information  
13 with the application:

- 14 1. The applicant's name, address, date of birth, and social security number;
- 15 2. Written documentation from two of the applicant's physicians that the applicant has been  
16 diagnosed with a debilitating medical condition as defined in regulation six and each  
17 physician's conclusion that the applicant might benefit from the medical use of marijuana;
- 18 3. The name, address, and telephone number of the two physicians who have concluded  
19 the applicant might benefit from the medical use of marijuana;
- 20 4. Consent from each of the applicant's parents residing in Colorado that the applicant may  
21 engage in the medical use of marijuana;
- 22 5. Documentation that one of the physicians referred to in ~~(iii)~~ (3) has explained the possible  
23 risks and benefits of medical use of marijuana to the applicant and each of the applicant's  
24 parents residing in Colorado; and
- 25 6. Indicate if a medical marijuana center has been designated to grow for the patient.

26 \*\*\*\*\*

27 I. Appeals. If the department denies an application or, suspends or, revokes a registry identification  
28 card, the department shall provide the applicant/patient with notice of the grounds for the denial,  
29 suspension, or revocation, and shall inform the patient of the patient's right to request a hearing.  
30 A request for hearing shall be submitted to the department in writing within thirty (30) calendar  
31 days from the date of the postmark on the notice.

- 32 1. If a hearing is requested, the patient shall file an answer within thirty (30) calendar days  
33 from the date of the postmark on the notice.

- 34 2. If a request for a hearing is made, the hearing shall be conducted in accordance with the  
35 ~~state~~ STATE Administrative Procedure Procedures Act, § 24-4-101, et seq., C.R.S.
- 36 3. If the patient does not request a hearing in writing within thirty (30) calendar days from  
37 the date of the notice, the patient is deemed to have waived the opportunity for a hearing.  
38

39 \*\*\*\*\*

#### 40 **Regulation 4: Change in applicant information**

- 41 A. When there has been a change in the name, address, physician or primary care-giver of a patient  
42 who has been issued a registry identification card, that patient must notify the department within  
43 ten days by submitting a completed ~~and notarized~~ Change of Address or Care-giver form as  
44 prescribed by the Department. A patient who has not designated a primary care-giver at the time  
45 of application to the department may do so in writing at any time during the effective period of the  
46 registry identification card, and the primary care-giver may act in this capacity after such  
47 designation. The Department shall not issue a new registry identification card to the patient on the  
48 sole basis of a new or change of primary care-giver.

49 \*\*\*\*\*

#### 50 **Regulation 6: Debilitating medical conditions and the process for adding new debilitating** 51 **medical conditions**

- 52 A. Debilitating medical conditions are defined as cancer, glaucoma, and infection with or positive  
53 status for human immunodeficiency virus. Patients undergoing treatment for such conditions are  
54 defined as having a debilitating medical condition.
- 55 B. 1. Debilitating medical condition also includes a chronic or debilitating disease or medical  
56 condition other than HIV infection, cancer or glaucoma; or treatment for such conditions,  
57 which produces for a specific patient one or more of the following, and for which, in the  
58 professional opinion of the patient's physician, such condition or conditions may  
59 reasonably be alleviated by the medical use of marijuana: cachexia; severe pain; severe  
60 nausea; seizures, including those that are characteristic of epilepsy; or persistent muscle  
61 spasms, including those that are characteristic of multiple sclerosis.
- 62 2. FOR APPLICATIONS RECEIVED BETWEEN SEPTEMBER 14, 2015 AND  
63 SEPTEMBER 14, 2019, AN ADDITIONAL DEBILITATING MEDICAL CONDITION FOR  
64 WHICH AN APPLICANT MAY APPLY FOR THE MEDICAL MARIJUANA PROGRAM  
65 REGISTRY INCLUDES POST-TRAUMATIC STRESS DISORDER (PTSD).
- 66 C. Patients who have had a diagnosis of a debilitating medical condition in the past but do not have  
67 active disease and are not undergoing treatment for such condition are not suffering from a  
68 debilitating medical condition for which the medical use of marijuana is authorized.
- 69 D. The department shall accept physician or patient petitions to add debilitating medical conditions  
70 to the list provided in paragraphs A and B of this regulation, and shall follow the following  
71 procedures in reviewing such petitions.
- 72 1. Receipt of petition; review of medical literature. Upon receipt of a petition, the executive  
73 director, or his or her designee, shall review the information submitted in support of the  
74 petition and shall also conduct a search of the medical literature for peer-reviewed  
75 published literature of randomized controlled trials or well-designed observational studies  
76 in humans concerning the use of marijuana for the condition that is the subject of the  
77 petition using PUBMED, the official search program for the National Library of Medicine  
78 and the National Institutes of Health, and the Cochrane Central Register of Controlled  
79 Trials.

- 80           2.       Department denial of petitions. The department shall deny a petition to add a debilitating  
81                    medical condition within (180) days of receipt of such petition without any hearing of the  
82                    board in all of the following circumstances:
- 83                    a.        If there are no peer-reviewed published studies of randomized controlled studies  
84                    nor well-designed observational studies showing efficacy in humans for use of  
85                    medical marijuana for the condition that is the subject of the petition;
- 86                    b.        If there are peer-reviewed published studies of randomized controlled trials or  
87                    well-designed observational studies showing efficacy in humans for the condition  
88                    that is the subject of the petition, and if there are studies that show harm, other  
89                    than harm associated with smoking such as obstructive lung disease or lung  
90                    cancer, and there are alternative, conventional treatments available for the  
91                    condition; OR
- 92                    c.        If the petition seeks the addition of an underlying condition for which the  
93                    associated symptoms that are already listed as debilitating medical conditions for  
94                    which the use of medical marijuana is allowed, such as severe pain, are the  
95                    reason for which medical marijuana is requested, rather than for improvement of  
96                    the underlying condition; ~~or.~~
- 97                    ~~d.        If a majority of the ad hoc medical advisory panel recommends denial of the~~  
98                    ~~petition in accord with paragraph (3) of this section D.~~
- 99            3.        IF THE CONDITIONS OF DENIAL SET FORTH IN PARAGRAPH (2) ARE NOT MET,  
100                   THE DEPARTMENT SHALL PETITION THE BOARD FOR A RULEMAKING HEARING  
101                   TO CONSIDER ADDING THE CONDITION TO THE LIST OF DEBILITATING MEDICAL  
102                   CONDITIONS.

103            [This editorial comment is informational and will not be included in the adopted rule: Lines 106-131  
104            have been repealed by the General Assembly through the rule review bill, SB 15-100. The repeal is  
105            effective May 15, 2015.]

- 106            ~~3.        Medical marijuana scientific advisory council.~~
- 107                    ~~a.        The medical marijuana scientific advisory council shall perform all of the following~~  
108                    ~~duties:~~
- 109                            ~~i.        Objectively evaluate research proposals and provide a peer review~~  
110                            ~~process that guards against funding research that is biased in favor or~~  
111                            ~~against particular outcomes for proposals submitted for the Colorado~~  
112                            ~~medical marijuana research grant program;~~
- 113                            ~~ii.       Provide policy guidance in the creation and implementation of the~~  
114                            ~~Colorado medical marijuana research grant program and in scientific~~  
115                            ~~oversight and review, and;~~
- 116                            ~~iii.       Review petitions to add a debilitating medical condition to the registry~~  
117                            ~~and make a denial or approval recommendation to the department.~~
- 118                    ~~b.        The medical marijuana scientific advisory panel council will review petitions to~~  
119                    ~~add debilitating medical conditions if the conditions for denial set forth in~~  
120                    ~~paragraphs (2)(A),(B) and (C) of this section d are not met. When reviewing~~  
121                    ~~petitions to add debilitating medical conditions to the registry, the ad hoc member~~  
122                    ~~of the council may be replaced by an ad hoc physician in the field relevant to the~~  
123                    ~~petition. Such individual may be recommended by the petitioner.~~
- 124                    ~~c.        The council shall review the petition information presented to the department and~~  
125                    ~~any further medical research related to the condition requested, and make~~

126 ~~recommendations to the executive director, or his or her designee, regarding the~~  
127 ~~petition.~~

128 ~~d. Within (120) days of receipt of a petition to add a debilitating medical condition,~~  
129 ~~the department shall petition the board for a rulemaking hearing to consider~~  
130 ~~adding the condition to the list of debilitating medical conditions if the council~~  
131 ~~recommends approval of the petition to add the condition.~~

132 4. Final agency action. The following actions are final agency actions, subject to judicial  
133 review pursuant to C.R.S. § 24-4-106:

134 a. Department denials of petitions to add debilitating medical conditions.

135 b. Board of health denials of rules proposed by the department to add a condition to  
136 the list of debilitating medical conditions for the medical marijuana program

137 \*\*\*\*\*

#### 138 **Regulation 14: Colorado medical research grant program**

139 A. Procedures for grant application to the grant program

140 1. Grant application contents.

141 a. At a minimum, all applications shall be submitted to the department in  
142 accordance with these rules and shall contain the following information:

143 i. A description of key personnel, including clinicians, scientists, or  
144 epidemiologists and support personnel, demonstrating they are  
145 adequately trained to conduct this research.

146 ii. Procedures for outreach to patients with various medical conditions who  
147 may be suitable participants in research on marijuana.

148 iii. Protocols suitable for research on marijuana as medical treatment  
149 including procedures for collecting and analyzing data and statistical  
150 methods to be used to assess significant outcomes.

151 iv. Demonstration that appropriate protocols for adequate patient consent  
152 and follow-up procedures are in place.

153 v. A process for a grant research proposal approved by the grant program  
154 to be reviewed and approved by an institutional review board that is able  
155 to approve, monitor, and review biomedical and behavioral research  
156 involving human subjects.

157 [This editorial comment is informational and will not be included in the adopted rule: Line 161 has been  
158 repealed by the General Assembly through the rule review bill, SB 15-100. The repeal is effective May  
159 15, 2015.]

160 2. Timelines for grant application.

161 ~~Grant applications may be solicited on dates determined by the department.~~

162 A. ABSENT APPROVAL FROM THE BOARD OF HEALTH, THE DEPARTMENT  
163 WILL SEEK APPLICATIONS NO MORE THAN THREE TIMES PER YEAR.

164 B. THE DEPARTMENT WILL NOTIFY PROSPECTIVE APPLICANTS OF THE  
165 OPPORTUNITY TO APPLY.

166 C. PROSPECTIVE APPLICANTS WILL HAVE A MINIMUM OF THIRTY DAYS TO  
167 APPLY.

168 D. APPLICATIONS WILL BE REVIEWED WITHIN 120 DAYS OF SUBMISSION  
169 AND REFERRAL OF RECOMMENDED APPLICATIONS TO THE BOARD OF  
170 HEALTH WILL BE WITHIN 180 DAYS OF SUBMISSION.

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