COLORADO
Department of Public Health & Environment

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To: Members of the State Board of Health

From: Tony Cappello, PhD, MPH, DCEED Director and Interim Environmental Epidemiology, Occupational Health, and Toxicology Branch Chief, Disease Control and Environmental Epidemiology Division (DCEED) ***TC***

Date: March 1, 2019

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

Please find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Comment, and Proposed Amendments to 5 CCR 1006-2 with a request for the Board of Health (Board) to adopt proposed revisions to Regulation 6 of this rule.

Section 14 of Article XVIII of the Colorado Constitution (referred to herein as "Constitution") requires the state health agency (Department) to enact rules of administration, including the manner in which the agency may consider adding debilitating medical conditions to the list of debilitating medical conditions established in the Constitution, see also Section 25-1.5-106(3)(a)(VII), C.R.S. The constitution further requires:

> "Beginning June 1, 1999, the state health agency shall accept physician or patient initiated petitions to add debilitating medical conditions to the list provided in this section and, after such hearing as the state health agency deems appropriate, shall approve or deny such petitions within one hundred eighty days of submission. The decision to approve or deny a petition shall be considered a final agency action."

The Department recommends modifying Regulation 6, the portion of the rule governing the process for adding debilitating conditions. The proposed revisions to the rule include language that has been updated and improved to: 1) align with the Department's current understanding of medical marijuana efficacy and administration, 2) reflect lessons learned while applying the current petition process, and 3) recognize the evolving body of evidence and standards from those that research medical marijuana and the other states that now authorize its use.

The goals of the proposed rulemaking are to:

1) Allow the Department and the Board to consider preliminary evidence of medical benefit for proposed conditions, which will provide an additional path from the current requirement that randomized controlled studies or well-designed observational studies are available to demonstrate benefit, and
2) Clarify the roles and responsibilities of the petitioner and the Department.

The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. The Department remains committed to engaging its stakeholders during this rulemaking period.

Because the proposed changes include a complete rewrite of Regulation 6, the proposed new text appears in ALL CAPS, with the current text of this regulation in strikethrough below. The Board provided feedback and asked for revisions to the proposal during the request for rulemaking presentation. Substantive changes since that presentation are highlighted in yellow.

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

Basis and Purpose.

In the November 2000 general election, Colorado voters passed Amendment 20 allowing patients with a qualifying medical condition to use medical marijuana. This Amendment was codified in Section 14 of Article XVIII of the Colorado Constitution. The Colorado Constitution and statutes provide broad authority to add a condition to the list of debilitating conditions and broad authority to promulgate rules governing the petition process. Specifically, the Colorado Constitution requires the state health agency (Department) to enact rules to administer the program, including rules that govern the manner in which the agency may consider adding debilitating medical conditions to the list provided in the Colorado Constitution, Article XVIII, Section 1(h) and (9). The rulemaking requirements are then elaborated upon in statute. Section 25-1.5-106(3)(a)(VII) states:

> "The state health agency shall, pursuant to Section 14 of Article XVIII of the state constitution, promulgate rules of administration concerning the implementation of the medical marijuana program that specifically govern the following… the manner in which the state health agency may consider adding debilitating medical conditions to the list of debilitating medical conditions contained in section 14 of article XVIII of the state constitution."

The 2018 Sunset Review of the Medical Marijuana Program by the Department of Regulatory Agencies, Colorado Office of Policy, Research, and Regulatory Reform (DORA COPRR) recommended that, "CDPHE should re-examine the process for adding to the list of debilitating medical conditions" (see Administrative Recommendation #3). The discussion of this recommendation reads:

> "In enumerating the list of debilitating medical conditions for which medical marijuana may be used, Amendment 20 allows for the delineation of additional conditions by directing the state health agency, which is CDPHE, to develop a process to add to the list. CDPHE has created a process that is rigorous, according to some, and impossible, according to others.
>
> The rules require peer-reviewed published studies of randomized controlled studies or well-designed observational studies showing the efficacy of the use of medical marijuana in humans for the condition that is the subject of the petition. On its face, this requirement appears reasonable. There should be scientifically demonstrable evidence to support the use of medical marijuana for a particular medical condition. However, the rules lack flexibility and instead dictate what must happen if such studies are not available. This is particularly problematic when discussing marijuana given its status under federal law. There is a remarkable dearth of the studies required by the rule.
>
> As a result, a total of 10 petitions have been submitted requesting the approval of 15 distinct conditions, yet only two—post-traumatic stress disorder (PTSD) and Tourette's syndrome—were referred to the Board of Health to consider the initiation of rulemaking proceedings to add them to the list of debilitating conditions. None have been added to

> the list, although the General Assembly created the concept of a disabling medical condition to enable sufferers of PTSD to legally use medical marijuana in the treatment of that condition.
>
> With more states legalizing both recreational and medical use of marijuana, it is reasonable to conclude that such studies will be conducted in the near future. But those studies may take years to complete and produce results. In the meantime, patients may be denied medical marijuana that may benefit them.
>
> Therefore, CDPHE should re-examine the process for adding to the list of debilitating medical conditions to, at a minimum, build in some flexibility for the review of petitions."
>
> Excerpt from 2018 Sunset Review: Medical Marijuana Program, DORA COPRR, page 47.

Furthermore, in June 2018, Governor Hickenlooper issued Executive Order (EO) 2018-004 that directs the Department to study whether Autism Spectrum Disorder (ASD) should be added to the list of debilitating conditions for the use of medical marijuana.[1] As directed by the EO, part of this study includes the Department evaluating and modifying the current rules, if needed, to recommend ASD as a qualifying debilitating condition, if the study found no significant health or development risk. While the Department has not completed its study of ASD and medical marijuana, it has found no randomized controlled trials or well-designed observational studies of ASD and marijuana. Because the petition process in current rule requires peer-reviewed published studies of randomized controlled studies or well-designed observational studies showing the efficacy of the use of medical marijuana in humans for the proposed medical condition, ASD cannot be added to the list of debilitating conditions without modifying the rules.

The Department is proposing to modify the current rules based on the EO, DORA COPRR sunset review, feedback from stakeholders and the Board, and the Department's experience with the petition process when reviewing the petition for PTSD. Specifically, the Department recommends modifying Regulation 6, which governs the process for adding debilitating conditions.

Currently, a petitioner needs to be a patient or physician, specify which condition they want to add, and to the extent known, provide a medical and scientific basis for why it is appropriate to add the condition. After submission of a petition, the Department reviews the submission and performs an independent analysis. If none of the criteria for denying a petition are met, the Department recommends a rulemaking hearing before the Board to consider adding the condition to the list of debilitating medical conditions. Under current rule, the Department is required to deny a petition if:

a. There are no peer-reviewed published studies of randomized controlled trials or well-designed observational studies showing efficacy in humans for the use of medical marijuana for the condition that is the subject of the petition;
b. There are studies that show harm, other than harm associated with smoking such as obstructive lung disease or lung cancer, and there are alternative, conventional treatments available for the condition; or

[1] This is the language provided in the Executive Order. The Department recognizes that studying the efficacy and administration to treat persons with ASD as the underlying condition is distinguishable from treating symptoms or co-occurring conditions for persons with ASD.

c. The petition seeks to add an underlying condition for which the associated symptoms are already listed as a debilitating medical condition and are the reason medical marijuana is requested, rather than for improvement of the underlying condition.

Because there are inherent barriers to conducting randomized controlled studies or well-designed observational studies using marijuana products, the proposed language in section C of Regulation 6 describes an additional pathway that allows for the submission of preliminary evidence so the Department may consider a petition that does not meet the current criteria. This additional pathway requires petitioners to submit the following information for consideration:

a. Published, peer-reviewed case reports or case series describing individuals with the proposed condition who experienced medical benefit as a result of using marijuana, and

b. Published, peer-reviewed evidence of biologic plausibility that demonstrates that marijuana use may confer medical benefit to individuals with the proposed condition.

c. If available, evidence of relative safety and unsatisfactory treatment options. If the petitioner is unable to evidence relative safety and unsatisfactory treatment options, the department can perform a search to see if such evidence is available. This may include evidence that shows the generally-accepted pharmaceutical treatments for the condition that show limited effectiveness, or show effectiveness but have limited acceptability due to the adverse effects profile, or evidence that shows the use of medical marijuana as a treatment for the condition is safe relative to other treatments, i.e. it is expected to have an adverse effects profile no worse than the adverse effects profiles of generally-accepted pharmaceutical treatments for the proposed condition.

If necessary, the department may engage subject matter experts to assist with their review of the petition.

The proposed rule language also recognizes that the Department can request amendments to petitions. The Department can assess whether the benefits or risks of medical marijuana treatment varies by the severity of the condition, a specific set of symptoms associated with the condition, or for a specific population of patients such as patients of a certain age and ask the petitioner to amend their petition accordingly.

Requiring such an amendment parallels the structure that exists in the Colorado Constitution. For example, the Constitution does not authorize medical marijuana for nausea but for severe nausea. If the added condition is qualified, it is anticipated it will be the responsibility of the recommending physician to communicate whether the severity, symptoms or sub-population components have been satisfied. It is not anticipated that this is a significant change in practice as a bona fide physician-patient relationship is already required and the recommending physician must already determine whether the patient would benefit from medical marijuana. Providing additional parameters will assist the physician with their examination and recommendation of medical marijuana.

If a petition qualifies a proposed condition in this manner, implementation through the Medical Marijuana Registry (MMR) is feasible. The MMR review process is designed to review an application to ensure the physician recommendation is for a recognized debilitating condition, or for a disabling condition defined in state statute. Adding qualifiers such as

"severe," "for patients with the following symptoms," or "for children over age 12" can be implemented within the current process.

The remainder of the proposed changes clarifies the roles and responsibilities of the petitioner and the Department; and clarifies that for any condition added by the Board, the Board can remove the condition through rulemaking, if additional information becomes available that would change the Department or Board's analysis regarding the condition or the safety, efficacy or medical benefit of using medical marijuana to treat the condition. The proposed changes to this rule also provides the Board with a recommended framework for reviewing a recommendation. This responds to Board of Health questions and discussion at the PTSD rulemaking hearing.

Specific Statutory Authority.

Colorado Constitution, Article XVIII, Section 1(h) and (9) and Section 25-1.5-106(3)(a)(VII), C.R.S.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.

__XX__ No

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library

__XX__ No

Does this rulemaking create or modify fines or fees?

_____ Yes

_XX___ No

Does the proposed rule create (or increase) a state mandate on local government?

_XX__ No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

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

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

   A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

   This portion of the rule is relied upon by patient or physician petitioners that seek to add a debilitating condition. Historically, the department has received less than one petition per year; the department anticipates the number of petitions will increase with this rule revision.

   B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:

   Future participants in the Medical Marijuana program, recommending physicians, caregivers, medical marijuana businesses, community-based or advocacy organizations that would like new debilitating conditions added, professional organizations such as the Colorado Medical Society or Colorado Association of Family Practitioners, and other states' Medical Marijuana programs.

   C. Identify each group of individuals/entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

   Potential future participants in the Medical Marijuana program, physicians who recommend treatment with medical marijuana, and the general public.

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.

   A. For those that rely on the rule to maintain their own businesses, agencies or operations:

   Favorable non-economic outcomes: As the proposed language expands the current petition process, the Department believes the proposed changes will:

   - Allow some petitions that would have been denied under the current rule to move forward in the petition process, thus, expanding the opportunity for the Board to gather written data and preliminary evidence and consider adding conditions that would not otherwise come to the Board.
   - Better inform patients, caregivers and recommending physicians as they consider whether the patient will benefit from medical marijuana.
   - More thoroughly communicate the Department's rationale for denying or advancing a petition.

Unfavorable non-economic outcomes: While the proposed changes lower the level of scientific evidence required, they do place an additional burden on the petitioner to provide preliminary evidence.

Favorable economic outcomes: Those who live and work in Colorado rely on the Department to fairly and consistently administer the Medical Marijuana program. The proposed changes to this rule allow for greater flexibility in the types of petitions heard by the Board, and clarifies the roles and responsibilities of the petitioner and the Department. Changing the rule to bring clarity and transparency to these roles will allow petitioners to more accurately and completely provide necessary information to the Department.

Unfavorable economic outcomes: N/A

B. For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.

Favorable non-economic outcomes: For petitions that result in adding a condition, increased physician recommendations and increased access to medical marijuana may occur.

Unfavorable non-economic outcomes: N/A

Any anticipated financial costs monitored by these individuals/entities? N/A

Any anticipated financial benefits monitored by these individuals/entities? For petitions that result in adding a condition, increased physician recommendations and increased access to medical marijuana may occur.

C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

Favorable outcomes, and, if known, the likelihood of the outcomes: The proposed rule will provide the medical marijuana community, Department and Board more opportunities to study whether medical marijuana would benefit, harm or increase risk to patients with a condition not current identified as a debilitating condition.
For petitions that result in adding a condition, more Colorado residents may have access to medical marijuana as a treatment for debilitating health conditions.

Unfavorable outcomes, and, if known, the likelihood of the outcomes: Future participants in the Medical Marijuana program may be at increased risk for unintended health consequences from the use of medical marijuana to treat their debilitating condition as the level of scientific evidence for adding conditions is less rigorous via the proposed additional pathway.

Financial costs to these individuals/entities: N/A

Financial benefits to or cost avoidance for these individuals/entities: N/A

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.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

Department staff have reached out to other states with Medical Marijuana programs to anticipate the type and number of petitions the Department may expect if the proposed changes to the petition process are adopted. There are approximately twelve eligible conditions in one or more states that are not identified on Colorado's list of debilitating conditions.

It is anticipated the Department will receive more petitions and thus, staff workload will increase. The Department's experience, which is comparable to the experience of Arizona and Washington staff, is extensive staff time is needed to process and review petitions. It is possible that the Department could receive multiple petitions at the same time, particularly in the first years of implementation. While Arizona receives four to eight petitions annually, an estimate of 10 has been utilized for this analysis in anticipation that the majority of 12 conditions recognized by other states would be submitted for consideration. The Colorado Constitution requires that a petition must be fully processed within 180 days; thus, the Department is required to process petitions as they come in and cannot establish a queue.

- The Department expects processing and review of a petition entails 80 to 120 hours of staff time, depending on the complexity of the proposed condition. Using an average of 100 hours and an assumption that 10 petitions will be received, this equates to approximately .5 FTE (100 x 10 = 1000 hours; 1.0 FTE equates to 2080 hours).
- If the petition is approved to proceed to the Board for consideration, additional resources will be needed to engage stakeholders, draft the rule and come before the Board. The resources allocated to rulemaking vary by the complexity of the regulatory proposal, size of the stakeholder group and the diversity in stakeholders interests. Using the staff time allocated to the rulemaking which proposed to add Post Traumatic Stress Disorder (PTSD) as a guide, it is anticipated that 80-160 hours are required to perform these activities. Stakeholders may be engaged on more than one condition at a time and the proposed rule may include more than one condition, which could generate some savings. However, because of the petition sequence and quick timeline, batching the petitions may not always be viable.
- While each petition would need to be reviewed in a manner that comports with the proposed rule, given that other states have added these conditions and to ensure adequate resources, the Department assumes 9 of the 10 petitions would advance to the Board of Health for its consideration. 80 - 160 hours x 9 = 720 - 1,440. This equates to 0.35 to 0.7 FTE (1.0 FTE equates to 2080 hours).
- Current practice for the Department is to review and process one petition at a time, over a six-month (180 days) time period.

In addition, if a petition is denied by the Department or the Board, the petitioner may seek judicial review. Staff time and legal services costs will be incurred to respond to litigation. These costs vary greatly depending upon the nature of the dispute and, thus, no estimate is provided.

Anticipated CDPHE revenues: Indeterminate.

The costs identified above constitute direct and indirect costs of operating the Medical Marijuana Registry program. The costs are covered by the fees collected from patients. The fee is set by the Board of Health. Additional revenue is generated when the fee is increased or when more patients apply for a Medical Marijuana Registry card. It is unknown if the proposed rule will result in the Board adding a condition to the list of debilitating conditions. It is further unknown that if a condition is added, that it will increase the number of patients participating in the Medical Marijuana Registry. It will vary based upon the number of patients with the condition and whether the individual is already participating in the registry for another debilitating condition. Using PTSD as an example, of the 90,247 patients participating in the registry, 8,000 identified PTSD as a condition and of the 8,000, 6,326 identified another qualifying debilitating condition at the time of application. With the application processing fee currently set at $25, Department revenues for patients with PTSD alone (1,674 patients) is $41,850.

The Medical Marijuana Registry manages the Medical Marijuana Cash Fund. Pursuant to Board rule, the fee is evaluated annually; however, it is monitored continuously. Based upon current revenues and spending authority, it is anticipated that the costs identified above can be covered without an increase in fees. If the fee needs to be adjusted, the Department will return to the Board of Health; if the spending authority, needs to be increased, the Department would need to submit that for the General Assembly's consideration. Alternatively, the Department can work with petitioners to ensure timely processing but at a rate that would not affect the fee patients pay.

B. Anticipated personal services, operating costs or other expenditures by another state agency: N/A

Anticipated Revenues for another state agency: N/A

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

Check mark all that apply:

___ Inaction is not an option because the statute requires rules be promulgated.

_X_ The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.

_X_ The proposed revisions appropriately maintain alignment with other states or national standards.

___ The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.

_X_ The proposed revisions implement stakeholder feedback.

___ The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and

Comply with statutory mandates and funding obligations

Strategies to support these goals:
___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
_X_ Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
___ Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
_X_ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
_X_ Establish infrastructure to detect, prepare and respond to emerging issues and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

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

This rulemaking is the only statutorily allowable method to act on DORA COPRR's Sunset Review, Administrative Recommendation #3 and enables the Department and Board to consider adding ASD as a debilitating condition, if no significant health or development risk is found, as directed by Executive Order 2018-004.

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

Few alternative methods for achieving the purpose of the proposed rules were considered because EO 2018-004 directs the Department to evaluate the rule, and if needed, modify current rules to enable the Department to perform its analysis and recommend ASD as a qualifying debilitating condition, if no significant health or development risk is found. In compliance with this EO, the Department has evaluated the current text of 5 CCR 1006-2 and determined that rule language in place today would not allow the Department to consider adding ASD as a debilitating condition if no significant health or development risk is found. Thus, the Department recommends modifying Regulation 6, the portion of the rule governing the process for adding debilitating conditions.

The Department received stakeholder feedback that the proposed changes to the rule should allow for patients and physicians to share their lived experience by documenting it in a letter and submitting it as part of a petition. During the request for rulemaking presentation, the Board indicated that while patient experience is relevant and important, it does not constitute scientific evidence. If the scientific and medical evidence is sufficient, patient experience can be included in the petition process if the Board sets the matter for a rulemaking hearing.

The Department received stakeholder feedback that the proposed changes to the rule should eliminate the petition process and list of disabling conditions altogether, and instead allow physicians to recommend medical marijuana for any condition they deem appropriate based on their training and experience. While this suggestion is aligned with

medical marijuana programs in other states (Oklahoma, and Washington), Article XVIII, Section 14(9) of the Colorado Constitution requires a petition process to add debilitating medical conditions to the list of conditions that could qualify an individual for the medical marijuana registry. As such, the Department has no authority to make this change.

The Department also received stakeholder feedback requesting reciprocity for medical marijuana cards between Colorado and other states with legalized medical marijuana. Neither the Colorado Constitution, nor the enabling statutes allow for reciprocity of medical marijuana cards with other states. Specifically, Article XVIII, Section 14 (1)(a) lists several debilitating conditions and also defines a debilitating condition as "Any other medical condition, or treatment for such condition, approved by the state health agency, pursuant to its rule making authority or its approval of any petition submitted by a patient or physician as provided in this section." As noted above, pursuant to the Colorado Constitution, the Department is required to review petitions for additional debilitating conditions to add them to the list of qualifying conditions. The proposed rules provide the structure for the Department to equitably and substantively review all petitions to determine whether a proposed debilitating medical conditions should be added to the list of debilitating medical conditions that may qualify an individual for the medical marijuana registry. A petition based solely on reciprocity does not provide the necessary information concerning the efficacy of medical marijuana for the condition or potential harms related to its use, and would not adhere to the proposed review standards.

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.

The Department interviewed several states with medical marijuana programs to learn more about the structure and function of their programs, petition process, and successes and challenges in each of those states. However, as this rulemaking was initiated based on an EO directive, and given restrictive statutory and constitutional language governing medical marijuana, there were few examples to follow or data to rely on.

The Department is proposing changes that would allow evaluation of a lower level of evidence. "Levels of evidence" is a concept common in evidence based medicine, such as discussed in this article: Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. Plast Reconstr Surg. 2011;128:305–10.

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

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Colorado medical marijuana card holders, members of the Retail Marijuana Public Health Advisory Committee, researchers at universities (local, national and international), local public health staff, marijuana industry representatives, pro-marijuana advocates and organizations, prevention and education professionals, anti-marijuana advocates and organizations, Colorado Chapter of the American Academy of Pediatrics, Colorado Academy of Family Physicians, Children's Hospital of Colorado, Colorado Medical Society, Colorado Psychiatric Society, Colorado Psychological Association, Smart Colorado, Autism Speaks Colorado, STRiVE, Northern Colorado Autism Association, Autism Society of Boulder County, and the Autism Society of Colorado.

Targeted outreach conducted and feedback:

- Initial emails were sent to all stakeholders listed above between October 18 and 24. These emails solicited feedback on the proposed changes to the rule through an online survey, directed interested recipients to the proposed changes and other information available via a Department webpage, and provided contact information for interested parties to contact Department staff involved in the rulemaking.
- The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. Thus far, 34 individuals and organizations have provided feedback through an online survey or through email communication. Several of the comments from stakeholders were outside the scope of this rulemaking, notably those requesting reciprocity of medical marijuana cards among states with legalized medical marijuana. One stakeholder suggested that the Department provide a checklist to petitioners to facilitate the submission of a complete petition and that the Department provide information on proposals submitted in the previous three years. Department staff will incorporate these suggestions on a dedicated webpage should the proposed changes to this rule be adopted.
- A few comments suggested that the Department provide a mechanism to allow direct input from the Colorado Medical Marijuana patient community in the rulemaking process. Medical marijuana patients, along with anyone else who is interested, will have an opportunity to submit written testimony or testify in person for any petition that is brought to the Board for consideration.

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was

provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

___ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

_XX_ Yes.

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.

Generally, patients, the medical marijuana community and the medical community appreciate the need to update the petition process and apply the learning that has occurred since the Constitutional amendment passed in 2000. At the request for rulemaking, the Board expressed concern that lowering the required level of evidence to demonstrate medical marijuana efficacy for proposed medical conditions could increase the possibility of adverse effects. The Board requested that the Department include an analysis of the current public health surveillance tools that could detect potential adverse effects as part of its review of petitions submitted to the Department. In addition, the Board asked for published, peer reviewed case studies of medical benefit and biologic plausibility to ensure the Department and the Board's decision-making is evidence-based. The Board also asked for the Department to clarify its role in the petition process to ensure that petitioners understood that the department would evaluate the evidence and determine whether the petition should advance to the Board for consideration. Based upon the level of scientific rigor desired by the Board, the proposed rule does not include letters as evidence to be considered during the scientific review.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Overall, after considering the benefits, risks and costs, the proposed rule:

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	X	Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the

	roles and responsibilities, or what occurs under a rule.		effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.

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John W. Hickenlooper
Governor

B 2018 004

EXECUTIVE ORDER

Directing the State Board of Health to Evaluate the Safety and Efficacy of Medical Marijuana for the Treatment of Autism Spectrum Disorders in Children

Pursuant to the authority vested in me by Article IV, Section 2 of the Colorado Constitution and the laws of the state of Colorado, I, John W. Hickenlooper, Governor of the State of Colorado, hereby issue this Executive Order directing the State Board of Health to evaluate the safety, and efficacy, of medical marijuana for the treatment of autism spectrum disorders in children.

I. Background and Purpose

According to the Centers for Disease Control and Prevention, Autism Spectrum Disorder (ASD) affects one in 72 children in Colorado and one in 59 nationally. Males experience ASD at higher rates than females (one in 37 versus one in 151 nationally). Children and adults with this developmental disability suffer significant social and behavioral challenges. People with ASD have a variety of different symptoms that range from mild to very severe, making diagnosis and prevalence tracking particularly challenging.

Colorado has taken steps to ensure that children with ASD can access the care and treatment they need. Colorado provides coverage for some services for ASD as part of its Medicaid benefit and Colorado insurance law prohibits visit and dollar limits on ASD services. Still, too many parents across Colorado struggle to obtain access to the appropriate services for their children with ASD and to find treatment for the sometimes violent symptoms associated with this disability.

Many children with ASD, especially those with the most severe symptoms, are not well-served by the pharmaceuticals that currently exist for ASD treatment. Some parents of children who suffer from these extreme symptoms hope that medical marijuana may provide their child

and their family's relief. Anecdotal evidence, and limited case studies, from parents in the U.S. and abroad suggests that some children with ASD may be able to more effectively control their symptoms with medical marijuana. Rigorous clinical evidence does not currently exist to demonstrate that medical marijuana is safe and effective for children with ASD, and the Federal Food and Drug Administration has not approved any form of medical marijuana.

After the passage of Amendment 20, allowing for the use of marijuana for medicinal purposes, marijuana may be recommended by physicians to treat one of several "debilitating conditions." The Colorado Department of Public Health and Environment (CDPHE) has created a process that allows the State Board of Health to help determine whether a given condition should be added to the list of debilitating conditions. The medical and scientific experts at CDPHE, in consultation with the State Board of Health, can best weigh the medical safety and efficacy of the administration of medical marijuana to treat ASD.

II. Directives

The CDPHE and the State Board of Health shall consider whether ASD should be added to the list of debilitating conditions for the use of medical marijuana. In considering this addition, CDPHE, in coordination with the State Board of Health, shall:

- study the use of medical marijuana for ASD; and
- prioritize fiscal resources for the next round of MMJ research under the Medical Marijuana Health Research Grant Program to ensure funding is dedicated to researching use of MMJ by patients experiencing ASD.

This study shall:

- evaluate the safety and efficacy of MMJ for autism based on peer reviewed studies;
- encourage and invite direct participation by families with children experiencing ASD;
- conclude within 18 months of the signing of this Executive Order; and
- evaluate and, if needed, modify, current rules to enable CDPHE to perform its analysis and recommend ASD as a qualifying debilitating condition if no significant health or development risk is found; and
- if no significant health or development risk is found, modify existing rules or promulgate new rules authorizing ASD as a qualifying debilitating condition for use of MMJ until such time a significant health or development risk is found, if ever.

III. Duration

This Executive Order shall remain in effect until the State Board of Health completes the directives set forth above, or until it is terminated or extended by further executive order.

GIVEN under my hand and the Executive Seal of the State of Colorado, this sixth day of of June, 2018.

Donna Lynne
Lt. Governor, acting on behalf of the State while Governor John W. Hickenlooper is absent from the State.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Center for Health and Environmental Data

MEDICAL USE OF MARIJUANA

5 CCR 1006-2

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Regulation 6: Debilitating medical conditions and the process for adding new debilitating medical conditions

A. DEFINITIONS. THE DEFINITIONS DESCRIBED HERE ONLY PERTAIN TO REGULATION 6.

1. ADVERSE EFFECTS - EFFECTS A RECOGNIZED TREATMENT IS KNOWN TO HAVE THAT ARE PHYSICALLY OR MENTALLY HARMFUL OR UNDESIRABLE TO SOME PATIENTS UNDERGOING THE TREATMENT.

2. PUBLISHED - REFERS TO RESEARCH THAT HAS BEEN PUBLISHED IN A PEER-REVIEWED SCIENTIFIC JOURNAL INDEXED IN MEDLINE (WWW.NCBI.NLM.NIH.GOV), SCOPUS (WWW.SCOPUS.COM), WEB OF SCIENCE (WWW.WEBOFKNOWLEDGE.COM), OR LISTED IN THE DIRECTORY OF OPEN ACCESS JOURNALS (WWW.DOAJ.ORG).

3. RECOGNIZED MEDICAL CONDITION - A MEDICAL CONDITION THAT IS GENERALLY ACCEPTED BY THE MEDICAL COMMUNITY AND OTHER EXPERTS AS A VALID, EXISTING MEDICAL CONDITION, AND THAT CAN BE ACCURATELY DIAGNOSED BY A PHYSICIAN.

4. RECOGNIZED TREATMENT - A TREATMENT OF THE MEDICAL CONDITION THAT IS GENERALLY ACCEPTED BY THE MEDICAL COMMUNITY AND OTHER EXPERTS AS A VALID, EXISTING MEDICAL TREATMENT, AND IS ROUTINELY USED BY PHYSICIANS TREATING THE PROPOSED MEDICAL CONDITION.

B. DEBILITATING MEDICAL CONDITIONS. SECTION 14 OF ARTICLE XVIII OF THE COLORADO CONSTITUTION ALLOWS FOR THE MEDICAL USE OF MARIJUANA FOR PERSONS SUFFERING FROM DEBILITATING MEDICAL CONDITIONS.

1. THE ARTICLE SPECIFIES THE FOLLOWING DEBILITATING MEDICAL CONDITIONS:

   a. CANCER, GLAUCOMA, POSITIVE STATUS FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV), ACQUIRED IMMUNE DEFICIENCY SYNDROME, OR TREATMENT FOR SUCH CONDITIONS.

   b. A CHRONIC OR DEBILITATING DISEASE OR MEDICAL CONDITION, OTHER THAN HIV INFECTION, CANCER, OR GLAUCOMA, OR TREATMENT FOR SUCH CONDITIONS, WHICH PRODUCES, FOR A SPECIFIC PATIENT, ONE OR MORE OF THE FOLLOWING, AND FOR WHICH, IN THE PROFESSIONAL OPINION OF THE PATIENT'S PHYSICIAN, SUCH CONDITION OR CONDITIONS

REASONABLY MAY BE ALLEVIATED BY THE MEDICAL USE OF MARIJUANA: CACHEXIA; SEVERE PAIN; SEVERE NAUSEA; SEIZURES, INCLUDING THOSE THAT ARE CHARACTERISTIC OF EPILEPSY; OR PERSISTENT MUSCLE SPASMS, INCLUDING THOSE THAT ARE CHARACTERISTIC OF MULTIPLE SCLEROSIS.

2. PURSUANT TO THE DEPARTMENT'S RULEMAKING AUTHORITY, THE ARTICLE ALLOWS FOR THE ADDITION OF DEBILITATING MEDICAL CONDITIONS THROUGH PETITIONS SUBMITTED BY A COLORADO PATIENT OR PHYSICIAN.

C. **REQUIRED MEDICAL AND SCIENTIFIC CRITERIA FOR PETITIONS TO ADD A DEBILITATING MEDICAL CONDITION.** PETITIONS SUBMITTED TO THE DEPARTMENT FOR REVIEW MUST INCLUDE THE FOLLOWING:

1. PROPOSED MEDICAL CONDITION. A DESCRIPTION OF THE PROPOSED MEDICAL CONDITION, INCLUDING SYMPTOMS AND OTHER PHYSIOLOGICAL EFFECTS EXPERIENCED BY AN INDIVIDUAL SUFFERING FROM THE MEDICAL CONDITION OR RECEIVING TREATMENT FOR THE MEDICAL CONDITION, AND AN EXPLANATION OF HOW THESE ARE DEBILITATING IN SUCH A WAY THAT THEY CAUSE SEVERE SUFFERING AND IMPAIR THE ABILITY OF THE INDIVIDUAL TO ACCOMPLISH ACTIVITIES OF DAILY LIVING. APPLICABLE INTERNATIONAL CLASSIFICATION OF DISEASES, TENTH REVISION, CLINICAL MODIFICATION (ICD-10-CM) OR DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, 5TH REVISION (DSM-V) CODES SHOULD BE PROVIDED.

2. PROPOSED PATIENT POPULATION. A DESCRIPTION OF THE PROPOSED PATIENT POPULATION, INCLUDING ANY RESTRICTIONS ON PATIENT AGE (E.G. 18 YEARS OF AGE AND OLDER ONLY), OR QUALIFIERS ON THE SEVERITY OR SYMPTOM PROFILE (E.G. SEVERE PAIN ONLY) OF THE PROPOSED MEDICAL CONDITION THAT WOULD APPLY IF THE PETITION IS APPROVED.

3. TRADITIONAL SCIENTIFIC EVIDENCE OF MEDICAL EFFICACY OR EVIDENCE OF MEDICAL BENEFIT AND BIOLOGIC PLAUSIBILITY.

a. TRADITIONAL SCIENTIFIC EVIDENCE OF MEDICAL EFFICACY. DOCUMENTS SUPPORTING THE ASSERTION THAT THE USE OF MEDICAL MARIJUANA HAS DEMONSTRATED CLINICAL BENEFIT FOR THE PROPOSED MEDICAL CONDITION IN HUMAN SUBJECTS, AS DEMONSTRATED BY PUBLISHED RESEARCH DETAILING THE OUTCOMES OF RANDOMIZED CONTROLLED TRIALS OR WELL-DESIGNED OBSERVATIONAL STUDIES. GREATER WEIGHT WILL BE GIVEN TO SUCH PEER-REVIEWED DOCUMENTATION; OR

b. EVIDENCE OF MEDICAL BENEFIT AND BIOLOGIC PLAUSIBILITY. DOCUMENTS SUPPORTING THE ASSERTION THAT THE USE OF MEDICAL MARIJUANA HAS DEMONSTRATED MEDICAL BENEFIT AND BIOLOGIC PLAUSIBILITY FOR THE PROPOSED MEDICAL CONDITION, AS DEMONSTRATED BY:

i. PUBLISHED PEER-REVIEWED CASE REPORTS OR CASE SERIES DESCRIBING INDIVIDUALS WITH THE PROPOSED MEDICAL CONDITION WHO EXPERIENCED MEDICAL BENEFIT AS A RESULT OF USING MARIJUANA (MEDICAL OR OTHERWISE), AND

ii. PEER-REVIEWED, PUBLISHED STUDIES DESCRIBING ANIMAL MODEL(S) OF THE PROPOSED MEDICAL CONDITION FOUND THAT TREATING SUCH ANIMALS WITH MARIJUANA (MEDICAL OR

OTHERWISE) REDUCES THE ADVERSE EFFECT OF THE MEDICAL CONDITION, OR

iii. PEER-REVIEWED, PUBLISHED STUDIES THAT DESCRIBE THE BIOLOGICAL PROCESS AND DEMONSTRATE MARIJUANA (MEDICAL OR OTHERWISE) IMPACTS THIS BIOLOGICAL PROCESS IN A WAY THAT COULD REASONABLY BE EXPECTED TO PROVIDE MEDICAL BENEFIT FOR THE PROPOSED MEDICAL CONDITION. A SINGLE STUDY OR COMBINATION OF STUDIES MAY BE SUBMITTED TO SATISFY THIS REQUIREMENT.

4. RELATIVE SAFETY AND UNSATISFACTORY TREATMENT OPTIONS. IN ADDITION TO THE REQUIRED INFORMATION ABOVE, PETITIONS MAY INCLUDE EVIDENCE DOCUMENTING RELATIVE SAFETY AND UNSATISFACTORY TREATMENT OPTIONS. WHEN PETITIONS DO NOT INCLUDE THIS EVIDENCE, THE DEPARTMENT WILL ATTEMPT TO OBTAIN THIS EVIDENCE TO SUPPLEMENT PETITIONS. SUCH EVIDENCE IS NECESSARY FOR THE DEPARTMENT TO APPROVE A PETITION AND REQUEST A BOARD HEARING.

a. RELATIVE SAFETY. THE USE OF MEDICAL MARIJUANA AS A TREATMENT FOR THE PROPOSED MEDICAL CONDITION IS EXPECTED TO HAVE ADVERSE EFFECTS NO WORSE THAN THE ADVERSE EFFECTS OF CURRENTLY RECOGNIZED TREATMENTS FOR THE CONDITION. THE FOLLOWING EVIDENCE WILL BE USED TO COMPARE THESE:

i. EVIDENCE OF THE ADVERSE EFFECTS OF MARIJUANA USE (MEDICAL OR OTHERWISE), OTHER THAN HARM ASSOCIATED WITH SMOKING (E.G. OBSTRUCTIVE LUNG DISEASE OR LUNG CANCER), WILL COME FROM PUBLISHED RESEARCH ON THE HEALTH EFFECTS OF MARIJUANA OR FROM RESULTS OF CLINICAL TRIALS OF MARIJUANA-RELATED PHARMACEUTICALS, WHICH ARE AS APPLICABLE TO THE PROPOSED PATIENT POPULATION AS POSSIBLE.

ii. EVIDENCE OF RECOGNIZED TREATMENTS, THEIR EFFECTIVENESS, AND THEIR ADVERSE EFFECTS CAN BE ESTABLISHED BY ONE OF THE FOLLOWING:

1. ONE OR MORE PUBLISHED COMPREHENSIVE REVIEWS OF THE PROPOSED MEDICAL CONDITION THAT INCLUDES RECOGNIZED TREATMENTS USED FOR THE CONDITION, THEIR EFFECTIVENESS, THEIR POTENTIAL ADVERSE EFFECTS, AND THE FREQUENCY OF THOSE ADVERSE EFFECTS.

2. REPORTS OF ADVERSE EFFECTS FROM THE U.S. FOOD AND DRUG ADMINISTRATION'S MEDWATCH PROGRAM OR CLINICAL TRIALS FOR THE RECOGNIZED TREATMENT.

b. UNSATISFACTORY TREATMENT ALTERNATIVES. RECOGNIZED TREATMENTS FOR THE PROPOSED MEDICAL CONDITION ARE NOT SUFFICIENT TO ALLEVIATE THE DEBILITATION CAUSED BY THE MEDICAL CONDITION, OR SHOW EFFECTIVENESS BUT HAVE LIMITED ACCEPTABILITY DUE TO THE ADVERSE EFFECTS.

i. EVIDENCE OF RECOGNIZED TREATMENTS, THEIR EFFECTIVENESS AND THEIR ADVERSE EFFECTS CAN BE ESTABLISHED USING EVIDENCE AS DESCRIBED IN C.4.a.II.

c. IF A PETITIONER, AFTER MAKING A REASONABLE EFFORT IS UNABLE TO SUBMIT EVIDENCE OF RELATIVE SAFETY AND UNSATISFACTORY TREATMENT OPTIONS, THE PETITIONER MAY DOCUMENT THEIR GOOD FAITH EFFORT TO OBTAIN THIS EVIDENCE.

D. **DEPARTMENT REVIEW OF PETITIONS TO ADD DEBILITATING MEDICAL CONDITIONS.** UPON RECEIPT OF A PETITION THAT CONTAINS ALL OF THE INFORMATION REQUIRED IN SECTION C, THE DEPARTMENT SHALL REVIEW PETITIONS ACCORDING TO THE FOLLOWING:

1. PETITIONER REQUIREMENTS. PETITIONS MUST BE FILED BY A PATIENT RESIDING IN COLORADO OR A PHYSICIAN WHO MEETS THE PHYSICIAN REQUIREMENTS DEFINED IN REGULATION 8(A)(1) AND REGULATION 8(A)(4) OF THIS RULE. THE PETITIONER MUST PROVIDE THEIR NAME, ADDRESS, EMAIL ADDRESS, AND TELEPHONE NUMBER.

2. LIMITS ON PROPOSED MEDICAL CONDITIONS**.** PETITIONS MUST BE LIMITED TO ONE PROPOSED MEDICAL CONDITION. THE PROPOSED MEDICAL CONDITION MUST BE A RECOGNIZED MEDICAL CONDITION FOR WHICH THE CONDITION ITSELF AND/OR THE TREATMENT THEREOF CAUSE SEVERE SUFFERING AND IMPAIR THE ABILITY OF THE INDIVIDUAL TO ACCOMPLISH ACTIVITIES OF DAILY LIVING.

3. REQUIRED DOCUMENTATION**.** PETITIONS MUST INCLUDE MEDICAL AND SCIENTIFIC DOCUMENTATION, AS DESCRIBED IN SECTION C OF THIS REGULATION.

   a. IF A PREVIOUS PETITION TO ADD THE PROPOSED MEDICAL CONDITION HAS BEEN CONSIDERED WITHIN THE PAST 3 YEARS, THE PETITIONER MUST ALSO PROVIDE NEW PUBLISHED, PEER-REVIEWED EVIDENCE THAT WAS NOT AVAILABLE TO THE PETITIONER AT THE TIME OF THE PREVIOUS PETITION.

4. SUPPLEMENTAL EVIDENCE**.** FOR EACH PETITION RECEIVED, THE DEPARTMENT MAY CONDUCT A SEARCH OF THE MEDICAL LITERATURE FOR RELEVANT EVIDENCE INCLUDING EVIDENCE DESCRIBED IN SECTION C.3 AND C.4. THE DEPARTMENT MAY ALSO CONTACT SUBJECT MATTER EXPERTS WITH EXPERTISE IN OR RELATED TO THE PROPOSED MEDICAL CONDITION, OR SEEK INPUT FROM INFORMED MEMBERS OF THE MEDICAL MARIJUANA COMMUNITY TO ASSIST IN ITS ANALYSIS.

5. AMENDING A PETITION. THE DEPARTMENT MAY FIND THAT POTENTIAL BENEFITS OR HARMS ASSOCIATED WITH THE USE OF MARIJUANA (MEDICAL OR OTHERWISE) TO TREAT THE PROPOSED MEDICAL CONDITION VARY BASED ON THE TYPE OF PRODUCT, PATIENT POPULATION, OR OTHER FACTORS. IN SUCH CASES, THE DEPARTMENT MAY CONTACT THE PETITIONER AND ASK THE PETITIONER TO AMEND THE PETITION. EXAMPLES OF WHEN A PETITION MAY BE MODIFIED INCLUDE BUT ARE NOT LIMITED TO: RESTRICTING THE PETITION TO A SPECIFIC AGE GROUP OR A SUBSET OF PERSONS WITH THE PROPOSED MEDICAL CONDITION (E.G. A PERSON 18 YEARS OF AGE OR OLDER WITH SEVERE NAUSEA).

6. DENIAL OF A PETITION**.** THE DEPARTMENT SHALL DENY A PETITION TO ADD A DEBILITATING MEDICAL CONDITION, WITHOUT REQUESTING A RULEMAKING HEARING BY THE BOARD, IN ANY OF THE FOLLOWING CIRCUMSTANCES:

a. IF THE EVIDENCE AND DOCUMENTATION SUPPORTING THE PETITION IS INSUFFICIENT TO SATISFY THE CRITERIA IN SECTION C.

b. IF THE PROPOSED MEDICAL CONDITION IS DEBILITATING PRIMARILY BECAUSE OF A SYMPTOM OR SYMPTOMS FOR WHICH THE MEDICAL USE OF MARIJUANA IS ALREADY APPROVED ACCORDING TO SECTION B OF THIS REGULATION.

c. IF THE PROPOSED MEDICAL CONDITION IS ALREADY APPROVED AS A DEBILITATING CONDITION OR DISABLING CONDITION.

d. IF THE PETITION IS INCOMPLETE. IF COMPLETING THE PETITION WOULD REQUIRE ONLY SMALL CORRECTIONS OR ADDITIONS, THE DEPARTMENT MAY CONTACT THE PETITIONER AND ASK FOR DOCUMENTATION NECESSARY TO MAKE THE PETITION COMPLETE. ONCE THE PETITION IS COMPLETE, THE PETITION WILL BE REVIEWED WITHIN 180 DAYS OF THE PETITIONER RESUBMITTING THE PETITION. TO THE EXTENT POSSIBLE, THE DEPARTMENT'S DETERMINATION WILL BE MADE WITHIN 90 DAYS OF RECEIPT OF A COMPLETE PETITION.

e. IF A PETITION TO ADD THE REQUESTED MEDICAL CONDITION HAS BEEN PREVIOUSLY CONSIDERED WITHIN THE LAST 3 YEARS, AND NO NEW EVIDENCE HAS BEEN SUBMITTED BY THE PETITIONER.

f. THE PROPOSED MEDICAL CONDITION HAS ALREADY BEEN RECOGNIZED BY THE COLORADO GENERAL ASSEMBLY AS A DISABLING MEDICAL CONDITION, § 25-1.5-106 (a.7), C.R.S.

7. APPROVAL OF A PETITION AND REQUEST FOR A RULEMAKING HEARING. IF, UPON REVIEW, THE DEPARTMENT DETERMINES THAT: THE PETITION IS COMPLETE, AND THERE IS SUFFICIENT EVIDENCE THAT THE ANTICIPATED BENEFIT OF THE MEDICAL USE OF MARIJUANA OUTWEIGHS ANY ANTICIPATED HARMS ASSOCIATED WITH MARIJUANA USE (MEDICAL OR OTHERWISE) AMONG THE PROPOSED PATIENT POPULATION, THE DEPARTMENT WILL REQUEST THAT THE BOARD SCHEDULE A RULEMAKING HEARING TO REVIEW THE PETITION TO ADD THE PROPOSED MEDICAL CONDITION TO THE LIST OF DEBILITATING MEDICAL CONDITIONS. AS PART OF THE REQUEST FOR RULEMAKING, THE DEPARTMENT WILL PROVIDE THE BOARD:

a. THE PETITION,

b. THE DEPARTMENT'S RECOMMENDATION AS TO WHETHER THE PROPOSED MEDICAL CONDITION SHOULD BE ADDED TO THE LIST OF DEBILITATING MEDICAL CONDITIONS BASED ON THE DEPARTMENT'S ANALYSIS OF THE CRITERIA DESCRIBED IN SECTION C AND THE DEPARTMENT'S ANALYSIS OF WHETHER THE ANTICIPATED THERAPEUTIC BENEFITS OUTWEIGH THE ANTICIPATED HARM,

c. AN ASSESSMENT OF WHETHER THE DEPARTMENT CAN MONITOR ADVERSE EFFECTS OF MEDICAL MARIJUANA USED TO TREAT THE PROPOSED MEDICAL CONDITION, AND

d. SUCH OTHER INFORMATION THE DEPARTMENT, AT ITS DISCRETION, DEEMS RELEVANT.

8. DETERMINATION TIMEFRAME**.** TO THE EXTENT POSSIBLE, THE DEPARTMENT'S DETERMINATION WILL BE MADE WITHIN 90 DAYS OF RECEIPT OF A PETITION.

WHEN ISSUING A DETERMINATION, THE DEPARTMENT WILL EXPLAIN THE BASIS FOR ITS DECISION.

E. **BOARD RULEMAKING HEARING TO CONSIDER A PETITION TO ADD A DEBILITATING MEDICAL CONDITION.** FOR PETITIONS TO ADD A DEBILITATING MEDICAL CONDITION THAT THE DEPARTMENT REFERS TO THE BOARD FOR A RULEMAKING HEARING, THE BOARD WILL REVIEW THE PETITION, ANY ADDITIONAL MEDICAL, SCIENTIFIC OR TESTIMONIAL DOCUMENTS IDENTIFIED BY THE DEPARTMENT DURING THEIR REVIEW OF THE PETITION, AND ANY ADDITIONAL INFORMATION OR DOCUMENTATION PROVIDED BY THE PUBLIC, HEALTH PROFESSIONALS OR THE DEPARTMENT DURING THE RULEMAKING HEARING PROCESS. THE BOARD IS ENCOURAGED TO CONSIDER WHETHER THERE IS SUFFICIENT EVIDENCE THAT THE MEDICAL USE OF MARIJUANA IS MORE LIKELY THAN NOT TO PROVIDE THERAPEUTIC BENEFIT TO PATIENTS SUFFERING FROM THE CONDITION, AND THAT SUCH ANTICIPATED BENEFIT OUTWEIGHS ANY ANTICIPATED HARMS ASSOCIATED WITH MARIJUANA USE (MEDICAL OR OTHERWISE) AMONG THE PROPOSED PATIENT POPULATION. THE RULEMAKING HEARING WILL COMPLY WITH SECTION 24-4-103, C.R.S., AND SECTION 25-1.5-106(4), C.R.S.

F. **REMOVAL OR QUALIFICATION OF A DEBILITATING MEDICAL CONDITION FROM THE APPROVED LIST OF CONDITIONS.** FOR ANY MEDICAL CONDITION ADDED TO THE LIST OF DEBILITATING MEDICAL CONDITIONS THROUGH THE PETITION PROCESS, IF ADDITIONAL INFORMATION BECOMES AVAILABLE THAT WOULD CHANGE THE DEPARTMENT OR BOARD'S ANALYSIS, THE DEPARTMENT MAY INITIATE A RULEMAKING TO REMOVE OR QUALIFY THE CONDITION. THE RULEMAKING HEARING WILL COMPLY WITH SECTION 24-4-103, C.R.S., AND SECTION 25-1.5-106(4), C.R.S.

G. **FINAL AGENCY ACTION**. THE FOLLOWING ACTIONS ARE FINAL AGENCY ACTIONS, SUBJECT TO JUDICIAL REVIEW PURSUANT TO § 24-4-106, C.R.S.:

1. DEPARTMENT DENIALS OF PETITIONS TO ADD A MEDICAL CONDITION TO THE LIST OF DEBILITATING MEDICAL CONDITIONS.

2. BOARD DENIALS OF RULES PROPOSED BY THE DEPARTMENT TO ADD A MEDICAL CONDITION TO THE LIST OF DEBILITATING MEDICAL CONDITIONS.

3. BOARD ACTION TO REMOVE OR QUALIFY A MEDICAL CONDITION PREVIOUSLY ADDED TO THE LIST OF DEBILITATING MEDICAL CONDITIONS BY THE BOARD.

~~A. Debilitating medical conditions are defined as cancer, glaucoma, and infection with or positive status for human immunodeficiency virus. Patients undergoing treatment for such conditions are defined as having a debilitating medical condition.~~

~~B. Debilitating medical condition also includes a chronic or debilitating disease or medical condition other than HIV infection, cancer or glaucoma; or treatment for such conditions, which produces for a specific patient one or more of the following, and for which, in the professional opinion of the patient's physician, such condition or conditions may reasonably be alleviated by the medical use of marijuana: cachexia; severe pain; severe nausea; seizures, including those that are characteristic of epilepsy; or persistent muscle spasms, including those that are characteristic of multiple sclerosis.~~

~~C. Patients who have had a diagnosis of a debilitating medical condition in the past but do not have active disease and are not undergoing treatment for such condition are not suffering from a debilitating medical condition for which the medical use of marijuana is authorized.~~

~~D. The department shall accept physician or patient petitions to add debilitating medical conditions to the list provided in paragraphs A and B of this regulation, and shall follow the following procedures in reviewing such petitions.~~

~~1. Receipt of petition; review of medical literature. Upon receipt of a petition, the executive director, or his or her designee, shall review the information submitted in support of the petition and shall also conduct a search of the medical literature for peer-reviewed published literature of randomized controlled trials or well-designed observational studies in humans concerning the use of marijuana for the condition that is the subject of the petition using PUBMED, the official search program for the National Library of Medicine and the National Institutes of Health, and the Cochrane Central Register of Controlled Trials.~~

~~2. Department denial of petitions. The department shall deny a petition to add a debilitating medical condition within (180) days of receipt of such petition without any hearing of the board in all of the following circumstances:~~

~~a. If there are no peer-reviewed published studies of randomized controlled studies nor well-designed observational studies showing efficacy in humans for use of medical marijuana for the condition that is the subject of the petition;~~

~~b. If there are peer-reviewed published studies of randomized controlled trials or well-designed observational studies showing efficacy in humans for the condition that is the subject of the petition, and if there are studies that show harm, other than harm associated with smoking such as obstructive lung disease or lung cancer, and there are alternative, conventional treatments available for the condition;~~

~~c. If the petition seeks the addition of an underlying condition for which the associated symptoms that are already listed as debilitating medical conditions for which the use of medical marijuana is allowed, such as severe pain, are the reason for which medical marijuana is requested, rather than for improvement of the underlying condition.~~

~~3. If the conditions of denial set forth in paragraph (2) are not met, the department shall petition the board within 90 days of receipt of a petition for a rulemaking hearing to consider adding the condition to the list of debilitating medical conditions.~~

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

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

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

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