



To: Members of the State Board of Health

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Date: January 17, 2018

Subject: **Rulemaking Hearing**
Proposed Amendments to 5 CCR 1006-2, Medical Use of Marijuana, with a
request for the rulemaking hearing to occur in January 2018

The Medical Marijuana Registry (MMR) is proposing the following revisions to the Medical Use of Marijuana regulations. The Medical Marijuana Registry respectfully requests that the Board of Health amend the following:

- Alignment with Senate Bill 17-017 - Changes to regulations throughout the rule to align with Colorado Revised Statute Senate Bill 17-017 recognizing Post Traumatic Stress Disorder (PTSD) as a disabling medical condition. The proposed changes incorporate disabling medical conditions into the regulatory framework. In areas where statute established a different standard for individuals with a disabling medical condition, the distinction is represented in the proposed changes.
- Alignment with newly enacted House Bill 16-1373 - Changes to Regulation 9.J.4. to align with House Bill 16-1373, recognizing that a caregiver shall not “possess medical marijuana at school sponsored events”.
- Fee increase - Changes to Regulation 7 requesting a \$10 fee increase, bringing the total fee to a proposed \$25 starting in May, 2018. In 2014, the fee was temporarily reduced to \$15. Through process and system improvements, the Department extended the temporary reduction as long as possible. Based on current budget projections, a \$10 increase is needed to cover the direct and indirect costs to sustain the Medical Marijuana Registry Program, including critical services such as customer and technical support.
- Technical clean-up - Lastly, the Medical Marijuana Registry is proposing technical clean-up such as fixing typos, formatting discrepancies, and removing language that is no longer applicable due to processing efficiencies.

Track changes throughout the rule reflect proposed changes.

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

Basis and Purpose.

Overview of SB17-017 and proposed alignment

Pursuant to Section 14 of Article XVIII of the Colorado Constitution and §25-1.5-106, C.R.S., medical marijuana use is authorized for individuals with a debilitating medical condition. Debilitating medical conditions are identified in the Colorado Constitution. The State Board of Health is authorized to identify additional debilitating medical conditions. Medical marijuana use is authorized for individuals with a debilitating medical condition who participate in the Medical Marijuana Registry (MMR) program.

SB 17-017 created a second pathway for authorizing the use of medical marijuana for individuals with a disabling medical condition who participate in the MMR program. Disabling medical conditions are recognized in statute. Currently, Post-Traumatic Stress Disorder (PTSD) is the only disabling medical condition.

Upon review of the Colorado Constitution and §25-1.5-106, C.R.S., the Department has concluded that individuals with a disabling medical condition and individuals with a debilitating medical condition are treated similarly for purposes of the MMR program in the following areas:

- A bona fide physician-patient relationship is required.
- The term “patient” means an individual with a debilitating medical condition or a disabling medical condition. A patient with either a debilitating or disabling medical condition may apply for a registry identification card.
- Primary caregiver requirements are the same regardless of whether the caregiver is serving a patient with a debilitating medical condition or disabling medical condition so long as the primary caregiver is serving a non-minor patient.
- The parameters for a patient to use medical marijuana are the same regardless of the condition upon which MMR participation is based. Patients may not engage in the use of medical marijuana in a way that endangers the health or well-being of any person, or in plain view of or place open to the public regardless of the condition upon which MMR participation is based. A card will be revoked for one year if a patient violates these requirements.
- The parameters for a physician to certify to the department that a patient has a disabling or debilitating medical condition are the same if a physician is serving a non-minor patient.
- The department may deny a patient or primary caregiver application, or revoke a registry identification card regardless of the condition upon which MMR participation is based.
- Fees cover the direct and indirect costs of the program regardless of the condition upon which MMR participation is based.

Areas where individuals with a disabling medical condition and individuals with a debilitating medical condition are not treated similarly for purposes of the MMR program are:

- The physician certification process is different for minors with a disabling medical condition. For minors with a disabling medical condition, one of the two physicians that diagnose the patient as having a disabling medical condition must be a board-certified pediatrician, board-certified family physician or a board-certified child and adolescent psychiatrist. This physician is required to attest to being a part of the minor patient's primary care provider team. For a minor with a debilitating medical condition, any two physicians can diagnose the patient as having a debilitating medical condition; no attestation is required.
- Under the Colorado Constitution, applications for non-minors with a debilitating medical condition can have their application deemed approved if it takes the MMR program more than 35 days to process their application. Under §25-1.5-106(9), C.R.S., an application can be deemed approved if the application is not processed within 35 days regardless of the applicant's age. As written, a minor with a debilitating medical condition cannot have their application deemed approved, but under the statute a minor with a disabling medical condition can have their application deemed approved.

While this distinction can be relevant when law enforcement is assessing whether the individual's marijuana use is authorized, with the online application process, the average time for an application to be denied or approved is 1 day. Thus, reliance on an application rather than a registry identification card should be minimal.

- While the State Board of Health may add debilitating conditions, the statute does not authorize the State Board of health to add or modify disabling medical conditions through rulemaking. This authority rests solely with the General Assembly.

Upon review of the Colorado Constitution and §25-1.5-106, C.R.S., the Department identified inconsistencies in the statutory language. The Department has concluded that the requirements for patients, primary caregivers and physicians are to be applied equally regardless of the condition upon which application or MMR program participation is based. To reach this conclusion, the Department studied the statute as a whole, harmonizing conflicting language and allowing the more specific provision to apply. Additionally, the Department applied the statutory requirements and authorizations in a manner that affords patients, primary caregivers and physicians all of the following: a public process for evaluating the standards upon which MMR Program participation is based, notice of the standards applied to the individual, and due process in the event the department denies or revokes an application, or removes a physician from participation in the program and the individual is entitled to an administrative hearing pursuant to Article 4 of Title 24, C.R.S.

Areas where the statute was harmonized include:

- Rulemaking required under subsection (3)(a) affords patients with a disabling medical condition critical protections including rules that ensure confidentiality is maintained, an application form is available, medical information is verified, registry identification cards are issued and appropriately confirmed, and homebound patients can receive medical marijuana through a transporting primary caregiver. The Department has concluded that the rulemaking required pursuant to §25-1.5-106(3)(a), C.R.S. applies to MMR program activities regardless of whether application or participation is based on a debilitating medical condition or disabling medical condition.

SB17-017 did not modify the opening clause of subsection (3)(a)[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...] and thus, rulemaking required under this subsection is predicated on what is included in Colorado Constitution. The Colorado Constitution only contemplates debilitating medical conditions. The opening clause conflicts with the SB 17-017 revision to subsection

(3)(a)(VI) which expressly requires rules to address communications with law enforcement when a registry identification card has been suspended because the individual no longer has a debilitating medical condition *or disabling medical condition*. To harmonize this language, the department has relied upon the more specific language found at subsection (3)(a)(VI) and harmonized by the conflict by concluding that rulemaking is authorized.

Along with the internal conflict within subsection (3)(a), the opening clause of subsection (3)(a) and subsection (3)(a)(IV)(requiring rules for the development of a Department form that constitutes "written documentation" *as defined and used in section 14 of article XVIII of the state constitution*, which form a physician shall use when making a medical marijuana recommendation for a patient), conflicts with the rulemaking authorized in subsections (7)(d)(primary caregiver participation in the MMR program), (9)(registry identification card requirements) and (12)(parameters for authorized use of medical marijuana). Reading the statute in its entirety, the department concluded that incorporating disabling conditions into the rule effectuates the General Assembly's intent and affords applicants and MMR program participants' due process.

For example, SB17-017 directs that an individual with a disabling medical condition may apply to the registry, §25-1.5-106(9), C.R.S. A registry identification card may be denied or revoked; however, the applicant may appeal that determination under the Colorado Administrative Procedure Act, *id.* For an individual to exercise their appeal rights, the individual needs notice of the adverse determination and the basis upon which the determination is based. The rules provide the regulatory framework for the applicants and the department. If disabling medical conditions are not incorporated into the rule, the department would be relying solely on the statute and applicants with a disabling medical condition would not receive the due process of rules which enable public process, notice and uniform application by the state agency.

Similarly, SB17-017 modifies §25-1.5-106(5), C.R.S., such that a physician who certifies an individual for a debilitating medical condition or disabling medical condition comply with specific requirements. Pursuant to §25-1.5-106(6), C.R.S., if the department has reasonable cause to believe that a physician certifying an individual for a debilitating medical condition has violated the constitution, the statute or Board of Health rules, the physician may be referred to the Colorado Medical Board for investigation and determination. As with the rules governing the application process, the rules governing referrals to the Colorado Medical Board afford certifying physicians due process. SB17-017 modified the statute such that, if the department has reasonable cause that a physician certifying an individual for a disabling medical condition has violated the statute, the physician may be referred to the Colorado Medical Board for investigation and determination, §25-1.5-106(5), C.R.S. It is less clear as to whether a violation of the Board of Health rules can also serve as a basis for referral to the Colorado Medical Board; however, the "written documentation" requirement and verification rules required pursuant to subsection (3)(a) ensure that the MMR evaluation of physician certification is similar regardless of the condition the physician is certifying. To harmonize subsections (3), (5), and (6), protect patients and ensure due process is afforded, the Department has proposed the rule revisions below to ensure that physicians, regardless of what condition they may be certifying, are treated similarly, have public process and are notified of the process.

- §25-1.5-106(2)(a.7), C.R.S., defines "disabling medical condition" as Post Traumatic Stress Disorder as diagnosed by a licensed mental health provider or physician. A physician can make the diagnosis and complete the certification for MMR participation or a physician can review the diagnosis of a licensed mental health provider and determine if the patient would benefit from the medical use of marijuana. Ultimately a bona fide physician patient relationship is required and it is the physician's

responsibility for certifying a patient as having a disabling medical condition for which medical marijuana may be of benefit. The physician is accountable to their patient, the MMR program and the Colorado Medical Board for their certifications and the exemption from the criminal laws is afforded to physicians when operating within these parameters. The rules do not modify the physician certification process.

- Similarly, in reviewing the use of the word “diagnosis,” subsections (5)(d)(III), (9)(b) and (12)(b)(VII) all refer to physician diagnosis. There is only one instance where “diagnosis” does not specifically refer to “physician diagnosis.” §25-1.5-106(3)(a)(VI) requires rulemaking to establish standards for communications with law enforcement when a registry identification card has been suspended because the patient is “no longer diagnosed as having a debilitating medical condition.” In reading the statute as a whole, the Department has concluded that “diagnosed” as used in this subsection refers to the physician diagnosis that the patient has a disabling medical condition for which medical marijuana may be of benefit. The rule has not been modified to suspend a registry identification card when a licensed mental health provider communicates that the individual no longer has a disabling medical condition.

While statute authorizes the department to suspend the individual’s registry identification card when a physician notifies it that the disabling medical condition is no longer present, the MMR does not typically receive physician notifications of this nature. This may be because a registry identification card is valid for only year and in the event the debilitating condition resolved, the individual simply does not re-apply. It is unknown if physician notification that a condition has resolved will occur more often for disabling medical conditions but the department anticipates that the physician practice will be similar for both debilitating medical conditions and disabling medical conditions.

- Though the definition of primary caregiver at subsection (2)(d.5) was expanded to allow primary caregivers to serve patients with a debilitating or disabling medical condition and subsection (2.5)(i)(V) expressly requires parents to serve as a primary caregiver of a minor patient with a disabling medical condition, the definition of parent primary caregiver at subsection (2)(d.5)(i) was not expanded to acknowledge that a parent primary caregiver can serve a child with a disabling medical condition. Reading the statute as a whole, in order to effectuate the specific language at subsection (2.5)(i)(V), the department has applied the statute in a manner that requires a parent to serve as a primary caregiver to a child with either a disabling or debilitating medical condition.

For these reasons, the proposed changes incorporate disabling medical conditions into the regulatory framework. In areas where statute established a different standard for individuals with a disabling medical condition, the distinction is represented in the proposed changes.

Overview of alignment with newly enacted House Bill 16-1373

- House Bill 16-1373, subsection (d) (I) (A) addresses caregiver rules when administering prescribed medication. The proposed modification is to add language to regulation 9.J.4. to align with House Bill 16-1373, recognizing that a caregiver shall not “possess medical marijuana at school sponsored events”.

Overview of technical edits to align with current practice

- Under the current rule a patient may only update his or her caregiver information once a month. This requirement was put in place to manage the workload associated with modifying the patient’s record when mail was only method available to patients to make changes to their registration. With the implementation of the online system, patients can make changes to their registration online at any time without contacting

the Registry. Removing this limitation increases ease of use for both patients and Registry staff.

- Align the rule language with the MMR system enhancements by removing references to mail, forms and similar paper processes.
- Correct typos and grammatical errors.

Overview of the changes to the fee

Colorado Constitution, Article XVIII, Section 14, paragraph 9 directs the Board of Health (BOH) to enact rules for the administration of the program. Colorado Revised Statute §25-1.5-106 (16) authorizes the Board to set fees sufficient to meet the direct and indirect costs of administering the Medical Marijuana Registry. The Medical Use of Marijuana Regulations, 5 CCR 1006-2, Regulation 7.A requires the Registry to annually evaluate the amount of the fees to be charged to applicants and to propose fee modifications to the Board as appropriate.

The Department is proposing a registration fee increase from \$15 to \$25 to cover the direct and indirect costs of administering the MMR. Board of Health reduced the Medical Marijuana Registry application fee from \$35 to \$15 (effective February 1, 2014) to reduce a significant cash fund surplus in the Medical Marijuana Program Cash Fund. The \$15 fee structure was to be in place until the cash fund surplus was within the statutory limit of 16.5%, at which time it was understood that the fee would be restored to a level that would sustain the costs to administer the Registry.

In addition to the fee reductions identified above, the Medical Marijuana Registry Cash Fund surplus has been reduced over the past two years through the following legislative actions:

- \$10 million transferred to the Medical Marijuana Research Grant Program (SB 14-155),
- \$1,117,284 for a new Medical Marijuana Registration System (HB 14-1336- Long Appropriations Bill), and
- \$1,068,560 to support the development of the Department of Revenue's Caregiver Registry (SB 14-015).

The Department is not proposing that the \$35.00 fee be restored. The improvements to the Medical Marijuana Registration System have reduced application processing for online applicants time by reducing data entry, paper record searches, paper record management, card printing and mailing process. Many stakeholders have transitioned to the automated system seamlessly; however, there remains a need to provide customer service through increased phone support and technical assistance to patients, physicians and caregivers applying for or modifying their participation in the MMR. The proposed fee increase enables the Department to maintain and enhance this critical customer and technical support function.

House Bill 16-1211

The Registry has reviewed HB 16-1211, Licensing Marijuana Transporters for the purposes of the Medical Marijuana Registry and has determined that this bill does not affect our service of delivery. We are not proposing any changes or modifications to the rule relevant to this bill.

Summary of the proposed rule changes by section

Regulation 1 addresses confidentiality of the registry and provides definitions.

Summary of the changes:

Alignment with newly enacted SB 17-017:

- Expand the application requirements to include applicants with a disabling medical condition in Regulation 1.A.2a. and 1.C.5.

Rationale:

This modification implements SB 17-017 in a manner that ensures applicants and MMR program participants have public process, notice and due process. These changes are consistent with and implement subsection (9).

Regulation 2 delineates the requirements for applying for a registry identification card. This includes the required patient information, written documentation of the debilitating medical condition, proof of residency, application requirements for minors with a debilitating medical condition, timelines for a renewal application, a patient’s ability to change his/her primary caregiver, the criteria for rejecting or denying an application, revoking a registry identification card, requiring re-application, and the appeal procedures for applicants when this occurs.

Summary of the changes:

Alignment with newly enacted SB 17-017:

- Regulation 2.A.3. - Expand the application requirements to include applicants with a disabling medical condition.

Rationale:

These changes ensure individuals, regardless of condition, are treated similarly, have notice and receive due process. Colorado residency is required as neither the executive or legislative branches of Colorado have jurisdiction over individuals outside of the state of Colorado. Because the statute has different requirements for minor applications, these distinctions have been incorporated into the application process.

- Regulation 2.B.2. - Distinguish application requirements for minors with a debilitating condition and minors with a disabling medical condition.

Rationale:

These changes ensure individuals, regardless of condition, are treated similarly, have notice and receive due process. Colorado residency is required as neither the executive or legislative branches of Colorado have jurisdiction over individuals outside of the state of Colorado. Because the statute has different requirements for minor applications, these distinctions have been incorporated into the application process.

Technical Clean-up

- Regulation 2.D. - Remove requirement that a patient may change his or her primary care-giver with the department no more than once per month.

Rationale:

As a result of programmatic efficiencies gained from updating processes and the registration system, patients are no longer limited to the number of times they can change their primary caregiver

- Regulation 2.E.3. - Remove the reference to “mail” to recognize that communication can also occur by electronic means.

Rationale:

References to paper processes have been updated throughout the rule to acknowledge the both paper and online registration processes.

Regulation 3 requires verification of medical information, registry identification card contents, a non-minor applicant's ability to rely on an application in lieu of a registry identification card (35+ processing days), denying an application upon review of the medical information verification, and revocations for willful violations of the Colorado constitution.

Summary of the changes:

Alignment with newly enacted SB 17-017:

- Regulation 3.A. - Expand the application requirements and standards for denying and revoking a registry identification card to applicants and participants with a disabling medical condition.

Rationale:

These changes ensure individuals, regardless of condition, are treated similarly, have notice and receive due process. These changes are consistent with and implement subsections (9) and (3)(b).

Regulation 4 enables MMR patients to update their information or return his or her registry identification card.

Summary of the changes:

Alignment with newly enacted SB 17-017:

- Regulation 4.B. - Expand the application requirements and standards for changes to applicant information to applicants and participants with a disabling medical condition in.

Rationale:

These changes ensure individuals, regardless of condition, are treated similarly, have notice and receive due process.

Technical Clean-up

- Regulation 4.A. - Remove "Change of Address or Care-giver"

Rationale:

This change recognizes that patients may notify the department of changes to their registration electronic or paper form.

Regulation 5 establishes the standards for the department communicating suspended registry participation to law enforcement and law enforcement communicating constitutional or statutory violations to the department.

Summary of the changes:

Alignment with newly enacted SB 17-017

- Regulation 5.A. - Expand the authorized communications to incorporate disabling medical conditions.

Rationale:

These changes ensure alignment between the registry and law enforcement as required by subsections (3)(a)(VI), (7)(d) and (14).

Regulation 7 delineates the fees to cover the direct and indirect costs to administer the MMR program and indigent fee waiver requirements.

Summary of the changes:

Alignment with newly enacted SB 17-017

- Regulation 7.A - Expand the authorized determination of fees to incorporate disabling medical conditions.

Rationale:

Recognizes disabling medical condition with fees to cover the costs to administer the program.

Technical Clean-up

- Regulation 7.A. - Modify the fee amount from \$15 to \$25 and change the effective date to “May, 15, 2018.”

Rationale:

As discussed above, the proposed fee is necessary to cover the direct and indirect costs of maintaining the MMR program.

Regulation 8 delineates the physician requirements including the license to practice medicine, “in good standing” and bona-fide physician patient relationship standards as well as record-keeping and conflict of interest requirements. The rule also delineates reasonable cause referrals to the Colorado Medical Board, the basis for department sanctions, physician sanctions (revoking or suspending a physician’s ability to certify a debilitating medical condition), and the appeal process for physicians.

Summary of the changes:

Alignment with newly enacted SB 17-017

- Regulation 8.A., 8.A.1.a, 8.A.2., 8.A.2.a.ii., 8A.2.a.iii. - Expand the requirements to create a consistent standard for physicians regardless of the condition the physician has certified.

Rationale:

This modification provides critical procedural protection to physicians certifying individuals for a disabling medical condition. The proposed changes ensure physicians have public process, notice and due process. These changes ensure alignment between subsections (3)(a), (5) and (6).

Regulation 9 establishes the primary caregiver-patient relationship and primary caregiver rules.

Summary of the changes:

Alignment with newly enacted SB 17-017

- Regulation 9.J.7 and 9.L. - Expand the requirements to create a consistent standard for Primary care-giver-patient relationship and primary care-giver rules when providing medical marijuana for patients with a disabling medical condition.

Rationale:

This modification recognizes disabling medical conditions and establishes consistent standards for caregivers.

Alignment with newly enacted - HB 16-1373

- Regulation 9.J.4. - Add “or a school sponsored event” to align with HB 16-1373.

Rationale:

This modification expands the rule to recognize that a caregiver shall not possess medical marijuana school sponsored events in alignment with HB 16-1373.

Regulation 11 establishes the circumstances where an individual may be a transporting caregiver for a homebound patient. The rule delineates the criteria the department must consider when reviewing a waiver request, the term of a waiver, revocation standards, and the transporting caregiver’s appeal process.

Summary of the changes:

Technical Clean-up

- Regulation 11.A. - Remove “recommending form” and replace with “physician certification.”

Rationale:

This change recognizes the correct terminology being “physician certification” and will provide clarity for stakeholders reviewing the rule.

Regulation 12 requires patients to carry their registry identification card, authorizes a patient to redact specific personal identifying information from the card, and delineates when a card must be returned to the department. This rule prohibits certain actions and activities for MMR patients.

Summary of the changes:

Alignment with newly enacted SB 17-017

- Regulation 12.C.7. and 12.D.- Expand the requirements to create a consistent standard for MMR program participants regardless of the condition under which the individual applied.

Rationale: This modification implements SB 17-017 in a manner that ensures applicants and MMR program participants have public process, notice and due process. These changes are consistent with and implement subsection (9).

Technical Clean-up

- Regulation 12.A. - Add “who is using the services of a care-giver”

Rationale: This modification provides clarity that this section of the rule applies only to patients who are using the services of the caregiver.

- Regulation 12.B. - Remove “give a copy of the submitted form and replace with “notify their.”

Rationale: This change recognizes that patients may notify their caregiver of changes by electronically (automated system notifications) or by paper.

Regulation 13 establishes the criteria for processing a subpoena for Registry information.

Summary of the changes:

Technical Clean-up

- Regulation 13.A. - Strike “retuning” “after” and replace with “returning”.

Rationale:

- Technical edit to fix a typographical error.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes: Section 25-1.5-106, C.R.S.

Is this rulemaking due to a change in state statute?

Yes, the bill number is SB-17-017. Rules are authorized required.
 No

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

Yes
 No

Does this rulemaking incorporate materials by reference?

Yes
 No

If “Yes,” the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rulemaking 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.

Aligning with newly enacted SB 17-017

Aligning Board of Health Regulations with SB-17-017 to recognize Post-Traumatic Stress Disorder (PTSD) as a disabling medical condition will benefit Medical Marijuana registry stakeholders when reviewing the rules.

Technical Clean-up

Technical clean-up throughout the rule will benefit Medical Marijuana registry stakeholders as there are areas of the rule that currently have typos or language that is no longer applicable due to program efficiencies. This will assist Medical Marijuana stakeholders when reviewing the rules.

Fee Increase

The proposed \$10.00 fee increase will bring the total application processing fee to \$25.00. This fee increase will benefit Medical Marijuana registry stakeholders as it will cover the direct and indirect costs necessary to sustain the Medical Marijuana Registry Program, including services such as customer and technical support.

Although applicants will pay an additional \$10.00 in comparison to previous years, the Registry extended the temporary fee reduction as long as possible. Additionally, the proposed \$25 fee remains lower than the \$35 fee that was charged in 2013 prior to the temporary reduction.

This fee will allow the Medical Marijuana Registry Program to sustain customer service to its 180,000+ customers and stakeholders. Additionally, it allows the program to provide medical marijuana cards to patients within the statutorily required 35-day timeframe.

Implementation Timeline

October/November 2017: Announce fee increase proposal to stakeholders
January 17th, 2018: Board of Health Request for Rulemaking
February 2018: Official/formal public notice of rulemaking through BOH
March 2018: Board of Health Hearing (final rulemaking hearing)
May 15th, 2018: New Fee Effective Date

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.

Aligning with newly enacted SB 17-017

This alignment assists Medical Marijuana stakeholders when reviewing the rules.

Technical Clean-up

This will assist Medical Marijuana stakeholders when reviewing the rules.

Fee Increase

Based on the FY 2017-18 Schedule 9A Cash Fund Report analysis, the department has projected that a \$25 registration fee will be necessary to generate enough revenue to sustain the program through FY 2022-23 while also maintaining compliance with the 16.5% fund balance reserve limit with no addition fee adjustments expected during this timeframe.

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.
None
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.
- The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
- 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.
- 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
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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)
- 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)
- Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
- Establish infrastructure to detect, prepare and respond to emerging issues and respond to emerging issues (Goal 1, 2, 3, 4, and 5)
- Other favorable and unfavorable consequences of inaction:

Fee Increase - Inaction would require the Program to initiate substantial cost reduction efforts that would include a layoff of an estimated 5.0 FTE. This program reduction would result in significantly decreased customer service and an inability to provide responses sustain customer service to its 180,000+ customers and stakeholders. Additionally, it would result in the Program's inability to provide medical marijuana cards to patients within the statutorily required 35-day timeframe.

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

Aligning with newly enacted SB 17-017

No alternatives to rulemaking were considered as the proposed alignment of Board of Health Regulation and Statute is necessary to provide clarity and consistency.

Technical Clean-up

There is no less intrusive method to conduct technical cleanup of the rule.

Fee Increase

As the Medical Marijuana Registry is a fee-based program, increasing the fee is the only viable method to generate the revenue necessary to sustain the program. The \$15 fee structure was to be in place until the cash fund surplus was within the statutory limit of 16.5%, which occurred in FY17. It was understood that the fee would be restored to a level that would sustain the costs to administer the Registry.

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

Aligning with newly enacted SB 17-017

No alternatives to rulemaking were considered as the proposed alignment of Board of Health Regulation and Statute is necessary to provide clarity and consistency.

Technical Clean-up

There is no less intrusive method to conduct technical cleanup of the rule.

Fee Increase

No other alternatives to rulemaking were considered as Colorado Revised Statute §25-1.5-106 (16) authorizes the Board to set fees sufficient to meet the direct and indirect costs of administering the Medical Marijuana Registry. The Medical Use of Marijuana Regulations, 5 CCR 1006-2, Regulation 7.A requires the Registry to annually evaluate the amount of the fees to be charged to applicants and to propose fee modifications to the Board as appropriate. The Medical Marijuana Registry is a fee-based program, increasing the fee is the only viable method to generate the revenue necessary to sustain the program. The \$15 fee structure was to be in place until the cash fund surplus was within the statutory limit of 16.5%, which occurred in FY17. It was understood that the fee would be restored to a level that would sustain the costs to administer the Registry.

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 has determined that a fee increase will be required no later than May 2018 to sustain the program at its current level of functionality. The Department utilized FY 2017-18 Schedule 9A Cash Fund Report analysis in conjunction with a projection of current, average patient count of 88,000. Based on this projection, a \$25

application processing fee is projected to generate sufficient revenue to sustain the program through FY 2022-23 while also maintaining compliance with the 16.5% fund balance reserve limit with no addition fee adjustments expected during this timeframe.

Please see “Projection Calculations Table” below.

Projection Calculations

Including Fee Increase:		
Program Expenses	FY 2017-18 Expenses	Future Year Expenses
Personnel Services (18.6 FTE)	\$1,435,801	\$1,546,747
Division Administrative Expenses ^[N4]	\$58,531	\$58,531
Direct Operating Expenses	\$121,228	\$233,835
CDPHE Indirect costs (CDPHE overhead)	\$379,657	\$432,191
Total Expenses	\$1,995,217	\$2,271,304
Program Income	FY 2017-18 Income	Future Year Income
Fee ^[N6] Income - Current Fee, \$15	\$1,546,406	\$1,546,406
New Revenue generated by \$10 increase (effective date 5/15/17)	\$171,616	\$880,000
Return of unused funds allocated for MMRS system build	\$165,892	\$0
Interest Income	\$690	\$670
Total Income	\$1,884,604	\$2,427,076
Difference:	(\$110,613)	\$155,772

If Fee Increase is not approved:		
Program Expenses	FY 2017-18 Expenses	Future Year Expenses
Personnel Services (18.6 FTE)	\$1,435,801	\$1,546,747
Division Administrative Expenses ^[N4]	\$58,531	\$58,531
Direct Operating Expenses	\$121,228	\$233,835
CDPHE Indirect costs	\$379,657	\$432,191
Total Expenses	\$1,995,217	\$2,271,304
Program Income	FY 2017-18 Income	Future Year Income
Fee Income - Current Fee, \$15	\$1,546,406	\$1,546,406
Return of unused funds allocated for MMRS system build	\$165,892	\$0
Interest Income	\$690	\$670
Total Income	\$1,712,988	\$1,547,076
Difference:	(\$282,229)	*(724,228)

***The program has the responsibility to cover costs with appropriate fee revenue. Program will be out of compliance with statute if this fee is not approved.**

STAKEHOLDER COMMENTS
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:

The Department has worked with the Office of Attorney General to determine what is needed for the rules to not conflict with statute.

The Department distributed information about the proposed alignment with statute, fee increase and technical cleanup to the Medical Marijuana Registry Stakeholders lists. Stakeholder feedback will be collected through an online survey. This rulemaking will be publicized on the MMR website and survey results will be shared prior to the request for rulemaking hearing. The Department will review and incorporate feedback as appropriate.

Medical Marijuana Stakeholder groups:

- Medical Marijuana Registry Stakeholders (voluntary list serve open to anyone)
- Medical Marijuana Registry Physicians
- Medical Marijuana Registry Caregivers

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.

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.

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?

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	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 roles and responsibilities, or what occurs under a rule.	Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the 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.
	Other: _____ _____	Other: _____ _____

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

2 **Center for Health and Environmental Data**

3 **MEDICAL USE OF MARIJUANA**

4 **5 CCR 1006-2**

5 *[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

7 **Adopted by the Board of Health on November 18, 2015**

8 **Regulation 1: Establishment and confidentiality of the registry for the medical use of marijuana**

- 9 A. The Colorado Department of Public Health and Environment (“the department”) shall create and
10 maintain a confidential registry (“the registry”) of patients who have applied for and are entitled to
11 receive a registry identification card.
- 12 1. All personal medical records and personal identifying information held by the department
13 in compliance with these regulations shall be confidential information.
- 14 2. No person shall be permitted to gain access to any information about patients in this
15 registry, or any information otherwise maintained in the registry by the department about
16 physicians and primary care-givers of patients in the registry, except for authorized
17 employees of the department in the course of their official duties and authorized
18 employees of state and local law enforcement agencies which have stopped or arrested
19 a person who claims to be engaged in the medical use of marijuana and in possession of
20 a registry identification card issued pursuant to regulations two and three, or the
21 functional equivalent of the registry identification card.
- 22 a. Department employees may, upon receipt of an inquiry from a state or local law
23 enforcement agency, confirm that a registry identification card has been
24 suspended when a patient is no longer diagnosed as having a debilitating or
25 disabling medical condition.
- 26 b. Authorized department employees may respond to an inquiry from state or local
27 law enforcement regarding the registry status of a patient or primary care-giver
28 by confirming that the person is or is not registered. The information released to
29 state and local law enforcement must be the minimum necessary to confirm
30 registry status.
- 31 c. Authorized state and local law enforcement employees shall validate their inquiry
32 of a patient or primary care-giver by producing the registry identification card
33 number of a patient, or name, date of birth, and last four digits of the individual’s
34 social security number of the individual under inquiry if the person does not have
35 a registry identification card.
- 36 d. Authorized department employees may confirm a waiver for homebound or minor
37 patients’ transportation of medical marijuana from a medical marijuana center or
38 a waiver for a primary care-giver serving more than five patients, upon state or
39 local law enforcement inquiry. The minimum necessary information shall be
40 communicated to confirm or deny a waiver.
- 41 3. The department may release information concerning a specific patient to that patient with
42 the written authorization of such patient.

43 4. Primary care-givers and potential primary care-givers may authorize the inclusion of their
44 contact information in the voluntary caregiver registry maintained by the department to
45 allow authorized department staff to release their contact information to new registry
46 patients only in accordance with Regulation 9(c) below.

47 B. Any officer or employee or agent of the department who violates this regulation by releasing or
48 making public confidential information in the registry shall be subject to any existing statutory
49 penalties for a breach of confidentiality of the registry.

50 C. Definitions

51 1. An “adult applicant” is defined as a patient eighteen years of age or older.

52 2. A “minor applicant” is defined as a patient less than eighteen years of age.

53 3. “Council” means the medical marijuana scientific advisory council appointed by the
54 executive director of the Colorado department of public health and environment per
55 requirements established in section 25-1.5-106.5, C.R.S.

56 4. “Grant program” means the Colorado medical marijuana research grant program created
57 in section 25-1.5-106.5, C.R.S. to fund research intended to ascertain the efficacy of
58 administering marijuana and its component parts as part of medical treatment.

59 5. “Primary care-giver” or “primary caregiver” means a person other than the patient and the
60 patient’s physician, who is eighteen years of age or older and has significant
61 responsibility for managing the well-being of a patient who has a debilitating or disabling
62 medical condition. A primary caregiver may have one or more of the following
63 relationships:

64 a. A parent of a child as described by section (6) (e) of section 14 of article xviii of
65 the Colorado Constitution and anyone who assists that parent with caregiver
66 responsibilities, including cultivation and transportation;

67 b. An advising caregiver who advises a patient on which medical marijuana
68 products to use and how to dose them and does not possess, provide, cultivate,
69 or transport marijuana on behalf of the patient;

70 c. A transporting caregiver who purchases and transports marijuana to a patient
71 who is homebound; or

72 d. A cultivating caregiver who grows marijuana for a patient.

73 6. “Significant responsibility for managing the well-being of a patient” means that the
74 caregiver is involved in basic or instrumental activities of daily living. Cultivating or
75 transporting marijuana and the act of advising a patient on which medical marijuana
76 products to use and how to dose them constitutes a “significant responsibility.”

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

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

82 1. The applicant’s name, address, date of birth, and social security number;

83 2. At the time of application, the patient will indicate whether he or she will utilize a primary
84 care-giver or a medical marijuana center. Minor patients must have a primary care-giver
85 on record. Patients who are designated by their physician as homebound may request a
86 waiver to list both a primary care-giver and a medical marijuana center. If the primary

- 87 care-giver is not growing medical marijuana for the patient, the patient may designate a
88 medical marijuana center to grow his/her marijuana plants.
- 89 a. If a care-giver is selected on the application, the patient will identify the care-
90 giver's name and address. This information will be entered into the patient's
91 record and reflected on the registration card.
- 92 b. If a medical marijuana center is selected on the application, the patient's record
93 will reflect the patient has designated a medical marijuana center to grow his/her
94 marijuana. Specific medical marijuana center information will not be reflected on
95 the registration card nor in the patient record.
- 96 3. Written documentation from the applicant's physician that the applicant has been
97 diagnosed with a debilitating **or disabling** medical condition as defined in regulation six
98 and the physician's conclusion that the applicant might benefit from the medical use of
99 marijuana;
- 100 4. A statement from the physician if the patient is homebound, if applicable;
- 101 5. The name, address, and telephone number of the physician who has concluded the
102 applicant might benefit from the medical use of marijuana; and
- 103 6. A copy of a secure and verifiable identity document, in compliance with the Secure and
104 Verifiable Document Act, C.R.S. §24-72.1-101 et seq., for the patient and primary care-
105 giver, if any is designated.
- 106 7. Proof of residency must be established at time of application. Proof of residency must
107 contain a photograph and date of birth, the following can be used to establish Colorado
108 residency:
- 109 a. Valid state of Colorado driver's license;
- 110 b. Valid state of Colorado identification card; or
- 111 c. Any other valid government-issued picture identification that demonstrates that
112 the holder of the identification is a Colorado resident.
- 113 d. No combination of identification or documents may be used to establish
114 residency.
- 115 8. Applicants who are unable to provide the above-required proof of identification and/or
116 residency paperwork may submit a request for a documentation waiver. When evaluating
117 a request for waiver of the above proof of residency requirements, the department will
118 consider the totality of the valid documentation. Some factors that may be considered
119 when determining residency include:
- 120 a. Whether the applicant can document that his primary or principal home or place
121 of abode is in Colorado;
- 122 b. Whether the applicant can provide evidence of Colorado business pursuits, place
123 of employment, or income sources,
- 124 c. Whether the applicant can document Colorado residence for income or other tax
125 purposes;
- 126 d. If the applicant can document the age, residence of parents, spouse and
127 children, if any;
- 128 e. The situs of the applicant's personal and real property;

- 129 f. The existence of any other residences outside of Colorado and the amount of
130 time spent at each such residence;
- 131 g. Any motor vehicle or vessel registration, or;
- 132 h. Recent property tax receipts, recent income tax returns where a Colorado mailing
133 address is used as the primary address, current voter registration cards, or other
134 similar public records.
- 135 B. In order for a minor applicant to be placed in the registry and to receive a registry identification
136 card, the minor applicant must reside in Colorado and a parent residing in Colorado must consent
137 in writing to serve as the minor applicant's primary care-giver. Such parent must complete an
138 application form supplied by the department, and have such application signed and include fee
139 payment. The parent of the minor applicant must provide the following information with the
140 application:
- 141 1. The applicant's name, address, date of birth, and social security number;
- 142 2. Written documentation from two of the applicant's physicians that the applicant has been
143 diagnosed with a debilitating or disabling medical condition as defined in regulation six
144 and each physician's conclusion that the applicant might benefit from the medical use of
145 marijuana;
- 146 3. The name, address, and telephone number of the two physicians who have concluded
147 the applicant might benefit from the medical use of marijuana;
- 148 4. Consent from each of the applicant's parents residing in Colorado that the applicant may
149 engage in the medical use of marijuana;
- 150 5. Documentation that one of the physicians referred to in (3) has explained the possible
151 risks and benefits of medical use of marijuana to the applicant and each of the applicant's
152 parents residing in Colorado; and
- 153 6. Indicate if a medical marijuana center has been designated to grow for the patient.
- 154 C. To maintain an effective registry identification card, a patient must annually resubmit to the
155 department, at least thirty days prior to the expiration date, but no sooner than sixty days prior to
156 the expiration date, updated written documentation of the information required in paragraphs A
157 and B of this regulation.
158
159
- 160 D. ~~A patient may change his or her primary care-giver with the department no more than once per~~
161 ~~month.~~ A patient may change his or her primary care-giver by submitting such information on the
162 form and in the manner as directed by the department within ten days of the change occurring.
163 The department does not process patient requests to change his or her designated medical
164 marijuana center; a patient wishing to change his or her designated medical marijuana center
165 should reference the requirements established by the department of revenue's marijuana
166 enforcement division.
- 167 E. Rejected applications. Rejected applications shall not be considered pending applications, and
168 shall not be subject to the requirement in the Constitution that applications be deemed approved
169 after thirty-five days. The department may reject as incomplete any patient application for any of
170 the following reasons:
- 171 1. If information contained in the application is illegible or missing;
- 172 2. The physician(s) is/are not eligible to recommend the use of marijuana.

173 3. An applicant shall have (60) days from the date the department notifies the applicant
174 ~~mails~~ the rejected application to make corrections and resubmit the application.

175 F. Denied applications. The department may deny an application for any of the following reasons:

176 1. The physician recommendation is falsified;

177 2. Any information on the application is falsified;

178 3. The identification card that is presented with the application is not the patient's
179 identification card;

180 4. The applicant is not a Colorado resident;

181 5. If the department has twice rejected the patient's application, and the applicant's third
182 submission is incomplete.

183 If the department denies an application, then the applicant may not submit a new application until
184 six months following the date of denial and may not use the application as a registry card. If the
185 basis for denial is falsification, law enforcement shall be notified of any fraud issues.

186 G. The department may revoke a registry identification card for one year if the patient has been
187 found to have willfully violated the provisions of article xviii, section 14 of the Colorado
188 Constitution or C.R.S. § 25-1.5-106.

189 H. A patient who has been convicted of a criminal offense under article 18 of title 18, C.R.S.,
190 sentenced or ordered by a court to drug or substance abuse treatment, or sentenced to the
191 division of youth corrections shall be subject to immediate renewal of his/her registry identification
192 card. Such patient may only reapply with a new physician recommendation from a physician with
193 whom the patient has a bona fide relationship.

194 1. The patient shall remit the registry card to the department within 24 hours of the
195 conviction/sentence/court order.

196 2. The patient may complete and submit a renewal application for a registry card including a
197 new recommendation from a physician with a bona fide relationship.

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

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

205 2. If a request for a hearing is made, the hearing shall be conducted in accordance with the
206 State Administrative Procedure Act, § 24-4-101, et seq., C.R.S.

207 3. If the patient does not request a hearing in writing within thirty (30) calendar days from
208 the date of the notice, the patient is deemed to have waived the opportunity for a hearing.

209 **Regulation 3: Verification of medical information; issuance, denial, revocation, and form of**
210 **registry identification cards**

211 A. The department shall verify medical information contained in the patient's application within thirty
212 days of receiving the application. Verification of medical information shall consist of determining
213 that there is documentation stating the applicant has a current diagnosis with a debilitating or
214 disabling medical condition as defined in regulation six, by a physician who has a current active,
215 unrestricted and unconditioned license as defined in Regulation 8 to practice medicine issued by

216 the State of Colorado, which license is in good standing, and who has a bona fide physician
217 patient relationship with the patient as defined in regulation eight.

218 B. No more than five days after verifying medical information of the applicant, the department shall
219 issue a serially numbered registry identification card to the patient. The card shall state the
220 following:

221 i) The patient's name, address, date of birth, and social security number;

222 ii) That the patient's name has been certified to the department as a person with a
223 debilitating or disabling medical condition, whereby the person may address such
224 condition with the medical use of marijuana;

225 iii) The date of issuance of such card and the date of expiration, which shall be one year
226 from the date of issuance;

227 iv) The name and address of the patient's primary care-giver, if any is designated at the time
228 of application;

229 v) How to notify the department of any change in name, address, medical status, physician,
230 or primary care-giver.

231 C. Except for minor applicants, where the department fails within thirty-five days of receipt of
232 application to issue a registry identification card or fails to issue verbal or written notice of denial
233 of such application, the patient's application for such card will be deemed to have been approved.
234 "Receipt" shall be deemed to have occurred upon delivery to the department or deposit in the
235 United States mail. No application shall be deemed received prior to June 1, 2001.

236
237

238 D. The department shall deny the application if it determines that information has been falsified or it
239 cannot verify the medical information as provided in paragraph A of this regulation. A patient
240 whose application has been denied by the department may not reapply during the six months
241 following the date of denial. The denial of a registry identification card shall be considered a final
242 agency action.

243 E. In addition to any other penalties provided by law, the department shall revoke for a period of one
244 year the registry identification card of any patient found to have willfully violated the provisions of
245 Section 14 of Amendment 20 of the Colorado Constitution or the implementing legislation of
246 Section 14.

247 **Regulation 4: Change in applicant information**

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

256 B. A patient who no longer has a debilitating or disabling medical condition as defined in regulation
257 six shall return his registry identification card to the department within twenty-four hours of
258 receiving such information by his or her physician.

259 **Regulation 5: Communications with law enforcement officials about patients in the registry**

260 A. Authorized employees of state or local law enforcement agencies shall be granted access to the
261 information contained within the department's registry only for the purpose of verifying that an

262 individual who has presented a registry identification card to a state or local law enforcement
263 official is lawfully in possession of such card. The department shall report to authorized state or
264 local law enforcement officials whether a patient's registry identification card has been suspended
265 because the patient no longer has a debilitating or disabling medical condition.

266 B. Authorized employees of state or local law enforcement agencies shall immediately notify the
267 department when any person in possession of a registry identification card has been determined
268 by a court of law to have willfully violated the provisions of this section 14 of the Colorado
269 constitution or its implementing legislation, or has pled guilty to such offense.

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

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

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

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

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

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

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

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

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

308 c. If the petition seeks the addition of an underlying condition for which the
309 associated symptoms that are already listed as debilitating medical conditions for
310 which the use of medical marijuana is allowed, such as severe pain, are the

311 reason for which medical marijuana is requested, rather than for improvement of
312 the underlying condition.

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

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

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

319 b. Board of health denials of rules proposed by the department to add a condition to
320 the list of debilitating medical conditions for the medical marijuana program
321
322

323 **Regulation 7: Determination of fees to pay for administrative costs of the medical use of**
324 **marijuana program**

325 A. Application fee. Effective ~~May 15, 2018~~~~February 1, 2014~~, the ~~d~~Department shall collect ~~fifteen~~
326 ~~twenty five~~ dollars from each applicant at the time of application to pay for the direct and indirect
327 costs to administer the medical use of marijuana program, unless the applicant meets the criteria
328 set forth in section (b) of this Regulation (7) establishing indigence. Such fee shall not be
329 refundable to the applicant if the application is denied or revoked or if the patient no longer has a
330 debilitating or disabling medical condition. The amount of the fee shall be evaluated annually by
331 the department to ensure compliance with the applicable statutes and the fee meets the actual
332 Medical Marijuana Registry expenses. The department shall propose modifications to the board,
333 as appropriate. If the patient provides updated information at any time during the effective period
334 of the registry identification card, the department shall not charge a fee to modify the registry
335 information concerning the patient.

336 B. Indigence fee waiver. Any individual submitting an application for the registry may request an
337 indigence fee waiver if he or she submits at the time of application a copy of the applicant's state
338 tax return certified by the department of revenue that confirms that the applicant's income does
339 not exceed one hundred eighty-five percent of the federal poverty line, adjusted for family size.

340 C. Notification of indigent status. Individuals who meet the indigence standard after they have been
341 approved for the medical marijuana registry may complete a form, to be determined by the
342 department, notifying the department of their status and supplying a copy of the applicant's state
343 tax return certified by the department of revenue that confirms that the applicant's income does
344 not exceed one hundred eighty-five percent of the federal poverty line, adjusted for family size.
345 Upon receipt and confirmation of the information, the department shall issue a new medical
346 marijuana registry card for the remaining term of the current card noting said indigent status for
347 tax exemption purposes.

348 **Regulation 8: Physician requirements; reasonable cause for referrals of physicians to the**
349 **Colorado Medical Board; reasonable cause for department adverse action concerning**
350 **physicians; appeal rights**

351 A. **Physician Requirements.** A physician who certifies a debilitating or disabling medical condition
352 for an applicant to the medical marijuana program shall comply with all of the following
353 requirements:

354 1. **Colorado license to practice medicine.** The physician shall have a valid, unrestricted
355 Colorado license to practice medicine, which license is in good standing.

356 a. for the purposes of certifying a debilitating or disabling medical condition of an
357 applicant and recommending the use of medical marijuana for the medical
358 marijuana program, "in good standing" means:

- 359 i. The physician holds a doctor of medicine or doctor of osteopathic
360 medicine degree from an accredited medical school.
- 361 ii. The physician holds a valid license to practice medicine in Colorado that
362 does not contain a restriction or condition that prohibits the
363 recommendation of medical marijuana or for a license issued prior to
364 July 1, 2011, a valid, unrestricted and unconditioned; and
- 365 iii. The physician has a valid and unrestricted United States Department of
366 Justice federal drug enforcement administration controlled substances
367 registration.

368 2. **Bona fide physician patient relationship.** A physician who meets the requirements in
369 subsection A.1 of this Regulation 8 and who has a bona fide physician-patient
370 relationship with a particular patient may certify to the state health agency that the patient
371 has a debilitating or disabling medical condition and that the patient may benefit from the
372 use of medical marijuana. If the physician certifies that the patient would benefit from the
373 use of medical marijuana based on a chronic or debilitating or disabling disease or
374 medical condition, the physician shall specify the chronic or debilitating or disabling
375 disease or medical condition and, if known, the cause or source of the chronic or
376 debilitating or disabling disease or medical condition.

377 a. “Bona fide physician-patient relationship”, for purposes of the medical marijuana
378 program, means:

379 i. A physician and a patient have a treatment or counseling relationship, in
380 the course of which the physician has completed a full assessment of the
381 patient's medical history and current medical condition, including an
382 appropriate personal physical examination;

383 ii. The physician has consulted with the patient with respect to the patient's
384 debilitating or disabling medical condition before the patient applies for a
385 registry identification card; and

386 iii. The physician is available to or offers to provide follow-up care and
387 treatment to the patient, including but not limited to patient examinations,
388 to determine the efficacy of the use of medical marijuana as a treatment
389 of the patient's debilitating or disabling medical condition.

390 b. A physician making medical marijuana recommendations shall comply with
391 generally accepted standards of medical practice, the provisions of the medical
392 practice act, § 12-36-101 *et seq.*, C.R.S, and all Colorado Medical Board rules.

393 c. The “appropriate personal physical examination” required by paragraph A.2.a.i of
394 this Regulation 8 may not be performed by remote means, including
395 telemedicine.

396 3. **Medical records.** The physician shall maintain a record-keeping system for all patients
397 for whom the physician has recommended the medical use of marijuana. Pursuant to an
398 investigation initiated by the Colorado medical board, the physician shall produce such
399 medical records to the Colorado Medical Board after redacting any patient or primary
400 caregiver identifying information.

401 4. **Financial prohibitions.** A physician shall not:

402 a. Accept, solicit, or offer any form of pecuniary remuneration from or to a primary
403 caregiver, distributor, or any other provider of medical marijuana;

- 404 b. Offer a discount or any other thing of value to a patient who uses or agrees to
405 use a particular primary caregiver, distributor, or other provider of medical
406 marijuana to procure medical marijuana;
- 407 c. Examine a patient for purposes of diagnosing a debilitating or disabling medical
408 condition at a location where medical marijuana is sold or distributed; or
- 409 d. Hold an economic interest in an enterprise that provides or distributes medical
410 marijuana if the physician certifies the debilitating or disabling medical condition
411 of a patient for participation in the medical marijuana program.

412 B. **Reasonable cause for referral of a physician to the Colorado Medical Board.** For reasonable
413 cause, the department may refer a physician who has certified a debilitating or disabling medical
414 condition of an applicant to the medical marijuana registry to the Colorado Medical Board for
415 potential violations of sub-paragraphs 1, 2, and 3 of paragraph A of this rule.

416 C. **Reasonable cause for department sanctions concerning physicians.** For reasonable cause,
417 the department may sanction a physician who certifies a debilitating or disabling medical
418 condition for an applicant to the medical marijuana registry for violations of paragraph A.4 of this
419 rule. Reasonable cause shall include, but not be limited to:

420 1. The physician is housed onsite and/or conducts patient evaluations for purposes of the
421 medical marijuana program at a location where medical marijuana is sold or distributed,
422 such as a medical marijuana center, optional grow site, medically infused products
423 manufacturer, by a primary care-giver, or other distributor of medical marijuana.

424 2. A physician who holds an economic interest in an entity that provides or distributes
425 medical marijuana, such as a medical marijuana center, an infused products
426 manufacturer, an optional grow site, a primary care-giver, or other distributor of medical
427 marijuana.

428 3. The physician accepts, offers or solicits any form of pecuniary remuneration from or to a
429 primary care-giver, medical marijuana center, optional grow site, medically infused
430 product manufacturer, or any other distributor of medical marijuana.

431 4. The physician offers a discount or any other thing of value, including but not limited to a
432 coupon for reduced-price medical marijuana or a reduced fee for physician services, to a
433 patient who agrees to use a particular medical marijuana center, primary care-giver, or
434 other distributor of medical marijuana.

435 D. **Sanctions.** For reasonable cause, the department may propose any of the following sanctions
436 against a physician:

437 1. Revocation of the physician's ability to certify a debilitating or disabling medical condition
438 and recommend medical marijuana for an applicant to the medical marijuana registry; or

439 2. Summary suspension of the physician's ability to certify a debilitating or disabling medical
440 condition or recommend medical marijuana for an applicant to the medical marijuana
441 registry when the department reasonably and objectively believes that a physician has
442 deliberately and willfully violated section 14 of article xviii of the state constitution or § 25-
443 1.5-106, C.R.S. and the public health, safety and welfare imperatively requires
444 emergency action.

445 E. **Appeals.** If the department proposes to sanction a physician pursuant to paragraph c of this rule,
446 the department shall provide the physician with notice of the grounds for the sanction and shall
447 inform the physician of the physician's right to request a hearing.

448 1. A request for hearing shall be submitted to the department in writing within thirty (30)
449 calendar days from the date of the postmark on the notice.

- 450 2. If a hearing is requested, the physician shall file an answer within thirty (30) calendar
451 days from the date of the postmark on the notice.
- 452 3. If a request for a hearing is made, the hearing shall be conducted in accordance with the
453 state administrative procedures act, § 24-4-101 *et seq.*, C.R.S.
- 454 4. If the physician does not request a hearing in writing within thirty (30) calendar days from
455 the date of the notice, the physician is deemed to have waived the opportunity for a
456 hearing.

457 **Regulation 9: Primary care-giver-patient relationship and primary care-giver rules**

- 458 A. A patient who designates a primary care-giver for him or herself cannot also be a primary care-
459 giver to another patient.
- 460 B. A cultivating or transporting caregiver shall be listed as a primary caregiver for no more than five
461 patients in the medical marijuana registry at any given time unless a waiver as set forth in
462 Regulation Ten has been granted for exceptional circumstances.
- 463 C. An existing primary care-giver may indicate to the department at the time of registration on a form
464 to be developed by the department if the primary care-giver is available to serve more patients.
465 An individual who is not a registered primary care-giver, but who would like to become one may
466 submit contact information to the registry. The primary care-giver or prospective primary care-
467 giver shall waive confidentiality to allow release of contact information to physicians or registered
468 patients only. The department may provide the information but shall not endorse or vouch for any
469 primary care-giver or prospective primary care-giver.
- 470 D. A primary care-giver if asked by law enforcement shall provide a list of registry identification
471 numbers for each patient. If a waiver has been granted for a cultivating or transporting caregiver
472 to serve more than five patients, this will be noted on the department record of cultivating and
473 transporting care-givers and will be available for verification to law enforcement upon inquiry to
474 the department.
- 475 E. A primary care-giver shall have his/her primary registration card available on his/her person at all
476 times when in possession of marijuana and produce it at the request of law enforcement. The
477 only exception to this shall be when it has been more than thirty-five days since the date the
478 patient filed his or her medical marijuana application and the department has not yet issued or
479 denied a registry identification card. A copy of the patient's application along with proof of the
480 date of submission shall be in the primary care-giver's possession at all times that the primary
481 care-giver is in possession of marijuana. The primary care-giver may redact all confidential
482 patient information from the application other than the patient's name and date of birth.
- 483 F. A patient may only have one primary care-giver at a time.
- 484 G. A designated primary care-giver shall not delegate the responsibility of provision of medical
485 marijuana for a patient to another person.
- 486 H. A primary care-giver shall not join together with another primary care-giver for the purpose of
487 growing marijuana. Any marijuana grows by a care-giver shall be physically separate from grows
488 by other primary care-givers and licensed growers or medical marijuana centers, and a primary
489 care-giver shall not grow marijuana for another primary care-giver. If two or more care-givers
490 reside in the same household and each grows marijuana for their registered patients, the
491 marijuana grows must be maintained in such a way that the plants and/or ounces grown and or
492 maintained by each primary care-giver are separately identified from any other primary care-
493 givers plants and/or ounces.
- 494 I. A primary care-giver shall not establish a business to permit patients to congregate and smoke or
495 otherwise consume medical marijuana.
- 496 J. A primary care-giver shall not:

- 497 1. Engage in the medical use of marijuana in a way that endangers the health and well-
498 being of a person;
- 499 2. Engage in the medical use of marijuana in plain view of or in a place open to the general
500 public;
- 501 3. Undertake any task while under the influence of medical marijuana, when doing so would
502 constitute negligence or professional malpractice;
- 503 4. Possess medical marijuana or otherwise engage in the use of medical marijuana in or on
504 the grounds of a school or in a school bus or at a school sponsored event except when
505 the possession or use occurs in accordance with a school district board policy
506 established pursuant to § 22-1-119.3, C.R.S.;
- 507 5. Engage in the use of medical marijuana while:
- 508 a. In a correctional facility or a community corrections facility;
- 509 b. Subject to a sentence to incarceration; or c. In a vehicle, aircraft, or motorboat;
- 510 6. Operate, navigate, or be in actual physical control of any vehicle, aircraft, or motorboat
511 while under the influence of medical marijuana; or
- 512 7. Provide medical marijuana if the patient does not have a debilitating or disabling medical
513 condition as diagnosed by the person's physician in the course of a bona fide physician-
514 patient relationship and for which the physician has recommended the use of medical
515 marijuana.
- 516 K. A primary care-giver may charge a patient no more than the cost of cultivating or purchasing the
517 medical marijuana, and may also charge for care-giver services. Such care-giver charges shall be
518 appropriate for the care-giver services rendered and reflect market rates for similar care-giver
519 services and not costs associated with procuring the marijuana.
- 520 L. A primary care-giver shall have significant responsibility for managing the well-being of a patient
521 with a debilitating or disabling medical condition.

522 **Regulation 10: Waiver for primary care-givers to serve more than five patients**

- 523 A. In exceptional circumstances, a waiver may be granted by the department for the purpose of
524 allowing a primary care-giver to serve more than five patients. A separate waiver application will
525 be required by each patient seeking to use a primary care-giver who is already at the five patient
526 limit. If the department does not act upon the waiver application within 35 days, the waiver shall
527 be deemed approved until acted upon by the department.
- 528 B. Waiver applications shall be submitted to the department on the form and in the manner required
529 by the department.
- 530 C. The patient and primary care-giver shall provide the department such information and
531 documentation as the department may require validating the conditions under which the waiver is
532 being sought.
- 533 D. In acting on the waiver application, the department shall consider at a minimum all of the
534 following:
- 535 1. The information submitted by the patient applicant;
- 536 2. The information submitted by the primary care-giver;
- 537 3. County-wide prohibitions on medical marijuana centers;

- 538 4. The proximity of medical marijuana centers to the patient;
- 539 5. Whether granting the waiver would either benefit or adversely affect the health, safety or
540 welfare of the patient; and
- 541 6. What services beyond providing medical marijuana the patient applicant needs from the
542 proposed primary care-giver.
- 543 E. The department may specify terms and conditions under which any waiver is granted, and which
544 terms and conditions must be met in order for the waiver to remain in effect.
- 545 F. The term for the waiver shall be one year unless the care-giver reduces the number of patients he
546 or she serves during that year to five or fewer, at which time the waiver shall expire. The care-
547 giver shall notify the department in writing when he or she no longer provides care-giver services
548 to a patient.
- 549 G. At any time, upon reasonable cause, the department may review any existing waiver to ensure
550 that the terms and conditions of the waiver are being observed and or that the continued
551 existence of the waiver is appropriate.
- 552 H. The department may revoke a waiver if it determines that any one of the following is met:
- 553 1. The waiver jeopardizes the health, safety and welfare of patients;
- 554 2. The patient applicant or care-giver has provided false or misleading information in the
555 application;
- 556 3. The patient applicant or care-giver has failed to comply with the terms or conditions of the
557 waiver;
- 558 4. The conditions under which a waiver was granted no longer exist or have materially
559 changed; or
- 560 5. A change in state law or regulation prohibits or is inconsistent with the continuation of the
561 waiver.
- 562 I. The department will provide notice of the revocation of the waiver to the registered patient and
563 the care-giver at the time the waiver is revoked.
- 564 J. Appeals. If the department proposes to deny, condition, revoke or suspend a waiver for a primary
565 care-giver to serve more than five patients, the department shall provide the patient with notice of
566 the grounds for the action and shall inform the patient of the patient's right to request a hearing.
- 567 1. A request for hearing shall be submitted to the department in writing within thirty (30)
568 calendar days from the date of the postmark on the notice.
- 569 2. If a hearing is requested, the patient shall file an answer within thirty (30) calendar days
570 from the date of the postmark on the notice.
- 571 3. If a request for a hearing is made, the hearing shall be conducted in accordance with the
572 state Administrative Procedures Act, § 24-4-101 *et seq.*, C.R.S.
- 573 4. If the patient does not request a hearing in writing within thirty (30) calendar days from
574 the date of the notice, the patient is deemed to have waived the opportunity for a hearing.

575 **Regulation 11: Waiver for primary care-givers to deliver medical marijuana products from a**
576 **medical marijuana center.**

- 577 A. If the physician recommending the marijuana checks on the [physician certification](#) recommending
578 form that the patient is homebound, a waiver will be granted allowing a designated primary care-
579 giver to transport marijuana from a medical marijuana center to the patient.
- 580 B. The term for the waiver shall be the same as the effective dates of the patient's registry
581 identification card.
- 582 C. At any time, upon reasonable cause, the department may review any existing waiver to ensure
583 that the terms and conditions of the waiver are being observed and or that the continued
584 existence of the waiver is appropriate.
- 585 D. The department may revoke a waiver if it determines that any of the following are met:
- 586 1. The waiver jeopardizes the health, safety and welfare of patients;
- 587 2. The patient applicant has provided false or misleading information in the application;
- 588 3. The patient applicant has failed to comply with the terms or conditions of the waiver;
- 589 4. The conditions under which a waiver was granted no longer exist or have materially
590 changed; or
- 591 5. A change in state law or regulation prohibits or is inconsistent with the continuation of the
592 waiver.
- 593 E. Primary care-givers for minors shall have a waiver for transportation automatically granted as part
594 of a successful application process if the patient application indicates that the minor's primary
595 care- giver will be purchasing medical marijuana from a medical marijuana center. The term of
596 the waiver will coincide with the term of the registry identification card.
- 597 F. The department will provide notice of the revocation of the waiver to the patient and the primary
598 care- giver at the time the waiver is revoked.
- 599 G. Appeals. If the department proposes to deny, condition, revoke or suspend a waiver for a primary
600 care-giver to deliver medical marijuana products to a homebound patient, the department shall
601 provide the patient with notice of the grounds for the action and shall inform the patient of the
602 patient's right to request a hearing.
- 603 1. A request for hearing shall be submitted to the department in writing within thirty (30)
604 calendar days from the date of the postmark on the notice.
- 605 2. If a hearing is requested, the patient shall file an answer within thirty (30) calendar days
606 from the date of the postmark on the notice.
- 607 3. If a request for a hearing is made, the hearing shall be conducted in accordance with the
608 state Administrative Procedures Act, § 24-4-101 *et seq.*, C.R.S.
- 609 4. If the patient does not request a hearing in writing within thirty (30) calendar days from
610 the date of the notice, the patient is deemed to have waived the opportunity for a hearing.

611 **Regulation 12: Patient Responsibilities.**

- 612 A. A patient [who is using the services of a care-giver](#) shall provide his/her care-giver with a copy of
613 his/her application, physician certification and registration card, once issued. A copy of the
614 patient's application and registration card shall be in the primary care-giver's possession at all
615 times that the primary care-giver is in possession of marijuana. The patient may obscure or
616 redact the mailing address and social security number on the copy of the application or
617 registration card given to the primary care-giver.

- 618 B. When a patient changes his or her primary care-giver, the patient shall submit notice of the
619 change on the form and in the manner as directed by the department. The patient shall notify
620 their give a copy of the submitted form to the primary care-giver. The patient may obscure or
621 redact the mailing address and social security number on the copy of the form given to the
622 primary care-giver.
- 623 C. A patient shall not:
- 624 1. Engage in the medical use of marijuana in a way that endangers the health and well-
625 being of a person;
 - 626 2. Engage in the medical use of marijuana in plain view of or in a place open to the general
627 public;
 - 628 3. Undertake any task while under the influence of medical marijuana, when doing so would
629 constitute negligence or professional malpractice;
 - 630 4. Possess medical marijuana or otherwise engage in the use of medical marijuana in or on
631 the grounds of a school or in a school bus except when the possession or use occurs in
632 accordance with a school district board policy established pursuant to § 22-1-119.3,
633 C.R.S.;
 - 634 5. Engage in the use of medical marijuana while:
 - 635 a. In a correctional facility or a community corrections facility;
 - 636 b. Subject to a sentence to incarceration;
 - 637 c. In a vehicle, aircraft, or motorboat; or
 - 638 d. As otherwise ordered by the court.
 - 639 6. Operate, navigate, or be in actual physical control of any vehicle, aircraft, or motorboat
640 while under the influence of medical marijuana; or
 - 641 7. Use medical marijuana if the patient does not have a debilitating or disabling medical
642 condition as diagnosed by the person's physician in the course of a bona fide physician-
643 patient relationship and for which the physician has recommended the use of medical
644 marijuana.
- 645 D. A patient who no longer has a debilitating or disabling medical condition shall return his or her
646 registry identification card to the department within twenty-four hours of receiving such diagnosis
647 by his or her physician.
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- 650 E. A patient shall notify the department if convicted of a criminal offense under article 18 of title 18,
651 C.R.S., sentenced or ordered by a court to drug or substance abuse treatment, or sentenced to
652 the division of youth corrections. The patient shall be subject to immediate renewal of his/her
653 registry identification card. Such patient may only reapply with a new physician recommendation
654 from a physician with whom the patient has a bona fide relationship.
- 655 1. The patient shall remit the registry card to the department within 24 hours of the
656 conviction/sentence/court order.
 - 657 2. The patient may complete and submit a new application for a registry card including a
658 new recommendation from a physician with a bona fide relationship.
- 659 F. A patient shall not establish a business to permit other patients to congregate and smoke or
660 otherwise consume medical marijuana.

661 **Regulation 13: Subpoenas for Registry Information**

- 662 A. The department shall require that a fee be paid to the department for any subpoena served. The
663 fee shall be paid at the time of service of any subpoena upon the department plus a fee for meals
664 and mileage at the rate prescribed for state officers and employees in Section 24-9-104, C.R.S.
665 for each mile actually and necessarily traveled in going to and returning from the place named in
666 the subpoena. If the person named in the subpoena is required to attend the place named in the
667 subpoena for more than one day, there shall be paid, in advance, a sum to be established by the
668 department for each day of attendance to cover the expenses of the person named in the
669 subpoena.
- 670 B. The subpoena fee is \$200 for the first (4) hours of appearance or on-call or travel time to court,
671 excluding mileage, meals and lodging which shall be paid at state employee per diem rates.
672 Beyond the first (4) hours, the subpoena fee shall be the actual hourly rate of the witness
673 employee.
- 674 C. The subpoena fee shall not be applicable to any federal, state or local governmental agency, or to
675 a patient who has been determined to be indigent under the department.

676 **Regulation 14: Colorado medical research grant program**

- 677 A. Procedures for grant application to the grant program
- 678 1. In order to ensure objectivity in evaluating research proposals, the grant program shall
679 establish a scientific advisory council (council).
- 680 a. The council shall perform all of the following duties:
- 681 i. Provide policy guidance in the creation and implementation of the
682 research grant program and in scientific oversight and review.
- 683 ii. Objectively evaluate research proposals and provide a peer review
684 process that guards against funding research that is biased in favor of or
685 against particular outcomes.
- 686 iii. Submit recommendations to the department and the state board of
687 health for recommended grant recipients, grant amounts, and grant
688 duration.
689
- 690 2. Grant application contents.
- 691 a. At a minimum, all applications shall be submitted to the department in
692 accordance with these rules and shall contain the following information:
- 693 i. A description of key personnel, including clinicians, scientists, or
694 epidemiologists and support personnel, demonstrating they are
695 adequately trained to conduct this research.
- 696 ii. Procedures for outreach to patients with various medical conditions who
697 may be suitable participants in research on marijuana.
- 698 iii. Protocols suitable for research on marijuana as medical treatment
699 including procedures for collecting and analyzing data and statistical
700 methods to be used to assess significant outcomes
- 701 iv. Demonstration that appropriate protocols for adequate patient consent
702 and follow-up procedures are in place.

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

707 3. Timelines for grant application.

708 a. Absent approval from the board of health, the department will seek applications
709 no more than three times per year.

710 b. The department will notify prospective applicants of the opportunity to apply.

711 c. Prospective applicants will have a minimum of thirty days to apply.

712 d. Applications will be reviewed within 120 days of submission and referral of
713 recommended applications to the board of health will be within 180 days of
714 submission.

715 B. Criteria for selecting entities

716 1. The following criteria shall be used for selecting potential grantees:

717 a. The applicant submits a completed application in accordance with the
718 requirements in Section A.1;

719 b. The scientific merit of the research plan, including whether the research design
720 and experimental procedures are potentially biased for or against a particular
721 outcome.

722 c. The researchers' expertise in the scientific substance and methods of the
723 proposed research and their lack of bias or conflict of interest regarding the topic
724 of, and the approach taken in, the proposed research.

725 d. The applicant has the capacity to adequately administer and implement the grant
726 including the capacity to meet its responsibilities delineated in Section C.

727 2. The council shall submit recommendations for grants to the state board of health, which
728 shall approve or disapprove of grants submitted by the council. If the state board of
729 health disapproves a recommendation, the council may submit a replacement
730 recommendation within thirty days.

731 3. The state board of health shall award grants to the selected entities, specifying the
732 amount and duration of the award, which cannot exceed three years without renewal.

733 C. Grantee reporting

734 1. Progress reports. Grantees shall be responsible for ongoing reporting consisting of the
735 following:

736 a. Quarterly progress reports

737 b. Annual updates which may replace the fourth fiscal quarter report

738 c. Final report at the end of the grant cycle.

739 2. At a minimum, all progress reports, annual updates and final reports shall include the
740 numbers of patients enrolled in each study and any scientifically valid preliminary
741 findings.

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3. All progress reports, annual updates and final report shall be submitted to the Colorado medical marijuana research grant program. Reports shall be submitted electronically in any word processing software program compatible with Microsoft Word 2007 or higher format.
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4. Grantees who fail to submit any of the required reports may be terminated from the grant program for non-performance. In the event that grantees fail to submit a final report after the conclusion of their grant, future applications of the grantee may be denied based on prior non-performance.