



To: Members of the State Board of Health
From: Natalie Riggins, Manager, Medical Marijuana Registry Program, Center for Health and Environmental Data - *NAR*
Through: Chris Wells, PhD, MS, Director, Office of e-Health and Data, Center for Health and Environmental Data - *CSW*
Date: January 17, 2018
Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 5 CCR 1006-2, Medical Use of Marijuana, with a request for the rulemaking hearing to occur in March 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.
- Changes to Regulation 9.J.4. and 12.C.4 - Remove under the basis that the Medical Marijuana Registry does not have a role in school settings. Removing this provision keeps the roles and responsibilities of the Medical Marijuana Registry, schools and local governments clear.
- 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Registry is proposing technical clean-up such as fixing typos, formatting discrepancies, and removing language that is no longer applicable due to processing efficiencies.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 SB 17-017 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.

SB17-017 created a second pathway for authorizing the use of medical marijuana for individuals with a disabling medical condition who participate in the Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry participation is based.

- Fees cover the direct and indirect costs of the program regardless of the condition upon which Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 rejected or approved is 1 business 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 the 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry 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 Medical Marijuana Registry does not typically receive physician notifications of this nature. This may be because a registry identification card is valid for only one 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 changes to Regulation 9.J.4. and 12.C.4

Remove under the basis that the Medical Marijuana Registry does not have a role in school settings. Removing this provision keeps the roles and responsibilities of the Medical Marijuana Registry, schools and local governments clear.

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 the 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 Medical Marijuana Registry 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 Medical Marijuana Registry. The 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).

Enhancing Online System Functionality and Customer Support

The Registry has gained several efficiencies as a result of implementing the online Medical Marijuana Registry System (MMRS). Each day, the Registry receives and processes an average of 350 online applications, 250 emails and 150 phone calls. All online applicants who submit a complete and correct application are issued their medical marijuana registry identification card within 1 business day.

System efficiencies include:

- Faster processing times
- Improved and more secure electronic card format
- Real time ability for end users to update contact information, caregiver agreements, physician certifications, print card, display card on mobile device, receive automated notifications.
- Reduction of cards being lost, stolen, or delayed in the mail
- More efficient record management
- Reduced costs associated with card printing, card stock, office supplies, mailing costs, etc.

Although the online system brought many efficiencies to the program, it has identified a need for more robust customer support and ongoing system enhancements:

- **Customer Support:**
Prior to the online system, the Registry contracted with a 3rd party call center to provide phone support to customers. The majority of customer inquiries were related to the paper application process and card status, which the call center was equipped to answer adequately.

After the online system was launched in January of 2017, the Registry was inundated with inquiries from customers with requests for technical support related to Internet Service Providers (ISP), un-locking accounts, system navigation questions, general computer help, resetting passwords and how to submit an application processing fee. The call center did not have full access to the online system or the expertise to provide the necessary customer support.

In August of 2017, in an effort to meet the needs of customers, the Registry discontinued the contract with the 3rd party call center and began taking calls internally. This new and improved internal technical support has led to improved customer satisfaction.

- **System Enhancements:**
System functionalities evolve over time based on customer needs. The Registry is continually taking customer feedback and prioritizing future system enhancements to improve functionality and the overall customer experience. The Registry has already implemented the ability for customers to un-lock their accounts, which has improved the end user experience.

Another enhancement being implemented based on customer feedback is allowing applicants to submit corrected documentation within the system. Currently, when applicants submit invalid documentation such as IDs, Driver's licenses, invalid Social Security Numbers, or other incorrect documentation, they must email the Registry the required valid document or information. Through system enhancements customers will soon be able to submit corrected documentation in the online system.

The Registry is not proposing that the \$35 fee be restored. Budget projections indicate that a \$25.00 fee will cover customer support and ongoing system enhancements and other costs necessary to administer the Registry.

House Bill 16-1211

The Registry has reviewed HB 16-1211, Licensing Marijuana Transporters, and has determined that the Medical Marijuana Registry does not have a role in the transport of Medical Marijuana and Medical Marijuana-Infused products from one licensed establishment to another. 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:

- At Regulation 1.C.5 add the definition of "patient" but repeating the statutory definition of patient.

Rationale:

This modification implements SB 17-017 and helps the reader of the rule understand that the rule applies to all patients regardless of the medical condition upon which their application is based.

- 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 Medical Marijuana Registry program participants have public process, notice and due process regardless of condition. 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:

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.A, 2.B, 2.E.3. - Remove the reference to "form" or "mail" to recognize that communication can also occur by electronic means.

Rationale:

References to paper processes have been updated throughout the rule to acknowledge 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 3.B and C. - Align the processing times and card requirements so patients are treated similarly regardless of whether the individual has a debilitating or disabling condition, and specify that the 35-day application processing standard does not apply to minors with a debilitating condition.

Rationale:

These changes ensure individuals, regardless of condition, are treated similarly, have notice and receive due process. The constitutional requirements regarding the process for applications past the 35-day processing time does not apply to applications for minors with a debilitating medical condition but there is no similar exception in statute for minors with a disabling medical condition. These changes are consistent with and implement subsections (9) and (3)(b).

Regulation 4 enables Medical Marijuana Registry 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.

Rationale:

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

Technical Clean-up

- Regulation 4.A. - Remove reference to the Change of Address or Care-giver form.

Rationale:

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

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 Medical Marijuana Registry 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.

Fee Increase

- 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 Medical Marijuana Registry program.

Technical Clean-up

- Regulation 7.C. - Remove the reference to a "form".

Rationale:

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

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. through 8.D. 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.6 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.

Remove Regulation 9.J.4.

- Regulation 9.J.4. Remove: "Possess medical marijuana or otherwise engage in the use of medical marijuana in or on the grounds of a school or in a school bus or at a school sponsored event except when the possession or use occurs in accordance with a school district board policy established pursuant to § 22-1-119.3, C.R.S.;"

Rationale:

Remove under the basis that the Medical Marijuana Registry does not have a role in school settings. Removing this provision keeps the roles and responsibilities of schools and local governments clear.

Technical Clean-up

- Regulation 9.C. - Remove the reference to a "form".

Rationale:

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

Regulation 10 enables a primary caregiver to receive a waiver of the patient restrictions, which enables a caregiver to serve more than 5 patients in exceptional circumstances. The rule delineates the criteria the department must consider when reviewing a waiver request, the term of a waiver, revocation standards, and the primary caregiver's appeal process.

Technical Clean-up

- Regulation 10.B. - Remove the reference to a “form”.

Rationale:

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

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 Medical Marijuana Registry patients.

Summary of the changes:

Alignment with newly enacted SB 17-017

- Regulation 12.B. - Incorporate disabling medical conditions into the patient use provisions.

Rationale:

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

Remove Regulation 12.C.4.

- Regulation 12.C.4. Remove: “Possess medical marijuana or otherwise engage in the use of medical marijuana in or on the grounds of a school or in a school bus or at a school sponsored event except when the possession or use occurs in accordance with a school district board policy established pursuant to § 22-1-119.3, C.R.S.;

Rationale:

Removing this provision keeps the roles and responsibilities of schools and local governments clear as the Medical Marijuana Registry does not have a role in school settings.

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 references to a form.

Rationale: References to paper processes have been updated throughout the rule to acknowledge both paper and online registration processes. This change also recognizes that patients may notify their caregiver of changes 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

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.
 - Medical Marijuana Registry (MMR) Patients and Applicants with a Disabling Medical Condition
 - Medical Marijuana Registry patients and applicants in need for Medical Marijuana Registry services.
 - Clarity for individuals reading the rule.
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

Individuals with a disabling medical condition can now apply and participate in the Medical Marijuana Registry. The costs with submitting an application and the application fee may be offset by the price and availability of medical marijuana.

Changes to Regulation 9.J.4. and Regulation 12.B.4

Removing these provisions assists medical marijuana stakeholders when reviewing rules because it keeps the roles and responsibilities of the Medical Marijuana Registry, schools and local governments clear.

Technical Clean-up

This will assist Medical Marijuana stakeholders when reviewing the rules.

Fee Increase

Based on the FY 2017-18 fiscal 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. The fee increase will impact Medical Marijuana Registry patients.

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.

There was a nominal cost to update the Medical Marijuana Registry systems to acknowledge disabling medical conditions but this was necessary to comply with the SB 17-017. The remainder of the changes are clarifying and align with current practice.

Tables associated with the fee increase are available at the end of the Regulatory Analysis.

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

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 in order to sustain customer service to its 180,000+ customers and 90,000 patients. 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.

There is no less costly or less intrusive method. Rulemaking is necessary to change the fee. Aligning the rule with the newly enacted SB 17-017 ensures consistent processing and service to Medical Marijuana Registry patients. The remainder of the changes provide clarity and consistency.

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. Efforts were made to extend the current fee amount as long as possible. At the time of the fee reduction, it was understood that the fee would be restored to a level that would sustain the costs to administer the Registry once the cash fund reserve was within the statutory limitation. Every effort has been made to keep the fee low.

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

Rulemaking is the statutorily required mechanism to implement these changes for the reasons described in the Statement of Basis and Purpose. §25-1.5-106 (16), C.R.S., 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 minimum revenue necessary to sustain the program.

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 utilized FY 2017-18 Schedule 9A Cash Fund Report analysis in conjunction with a projection of current, average patient count of 88,000.

Projection Calculations

<u>Including Fee Increase:</u>		
Program Expenses	FY 2017-18	Future Year
Personnel Services (18.6 FTE)	\$1,435,801	\$1,546,747
Division Administrative Expenses	\$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	Future Year
Fee Income - Current Fee, \$15	\$1,546,406	\$1,546,406
New Revenue generated by \$10 increase (effective date 5/15/18)	\$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
<u>If Fee Increase is not approved:</u>		
Program Expenses	FY 2017-18	Future Year
Personnel Services (18.6 FTE)	\$1,435,801	\$1,546,747
Division Administrative Expenses	\$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	Future Year
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. The program will be out of compliance with statute if this fee is not approved and will not have the revenue necessary to sustain the Medical Marijuana Registry.***

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 distributed information about the proposed alignment with statute, fee increase and technical cleanup to the Medical Marijuana Registry (MMR) voluntary stakeholder email group. Stakeholder feedback was collected through an online survey in November 2017. Along with the online survey, stakeholders were invited to provide comments via email or U.S. mail.

Information about the January 2017 rulemaking, survey results, and information about how to submit final feedback to the Department has been publicized on the Medical Marijuana Registry website. The Medical Marijuana Registry continues to solicit feedback.

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.

The following themes and policy issues emerged in stakeholder feedback and comments.

Fee increase

Survey results show a lack of consensus regarding a proposed \$10 fee increase. Though there is lack of consensus, the Department is unable to accommodate the request to keep the fee at \$15, as the increase is needed to cover the direct and indirect costs to sustain the Medical Marijuana Registry program.

Customer support and online registration system

Some stakeholders provided comments about their experiences with the online system and customer service of the Medical Marijuana Registry program. These comments align with other customer feedback the Medical Marijuana Registry program has received since the launch of the online registration system.

Current and future plans to meet the needs of our customers include but are not limited to:

- Continuation of internal phone support
- Improved end user experience with the online system
- Faster response times for customer inquiries.

The proposed fee increase will allow the Medical Marijuana Registry program to continue to maintain and enhance these critical customer support functions as well as allow the Medical Marijuana Registry program to run more efficiently.

Changes to Regulation 9.J.4. and Regulation 12.B.4

Survey feedback indicated a lack of support for the Department's original proposed changes to align with House Bill 16-1373. To address this, the Department is proposing the removal of Regulation 9.J.4. and Regulation 12.C.4 under the basis that the Medical Marijuana Registry does not have a role in school settings. Removing this provision keeps the roles and responsibilities of the Medical Marijuana Registry program, schools and local governments clear.

Petition to add a debilitating medical condition added

Two survey respondents suggested adding qualifying conditions. The Department provided information about the process for petitioning to add a debilitating medical condition to two individuals who expressed interest in adding autism as a debilitating condition. It is not known if the survey respondents and these two individuals are the same persons.

Annual renewals

Survey feedback suggested the registration period be longer than one year. The Department is unable to accommodate this request, as the annual registration period is a constitutional mandate for debilitating conditions and a statutory mandate for debilitating and disabling medical conditions.

The Colorado Constitution requires the annual submission of a patient's written documentation. According to the Colorado Constitution Art. XVIII, Section 14, Provision (3)(f):

To maintain an effective registry identification card, a patient must annually resubmit, at least thirty days prior to the expiration date stated on the registry identification card, updated written documentation to the state health agency, as well as the name and address of the patient's primary care-giver, if any is designated at such time.

State statute mandates a one-year registry card and application process. Section 25-1.5-106(9)(c), C.R.S. reads,

A patient or primary caregiver registry identification card shall be valid for one year and shall contain a unique identification number. It shall be the responsibility of the patient or primary caregiver to apply to renew his or her registry identification card prior to the date on which the card expires. The state health agency shall develop a form for a patient or primary caregiver to use in renewing his or her registry identification card.

These requirements are communicated at Regulation 2.C.

Plant count

Survey results included feedback about plant count recommendations. Plant counts are established in Colorado Constitution and statute. The Department of Revenue’s Marijuana Enforcement Division is the lead agency for cultivation matters.

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?

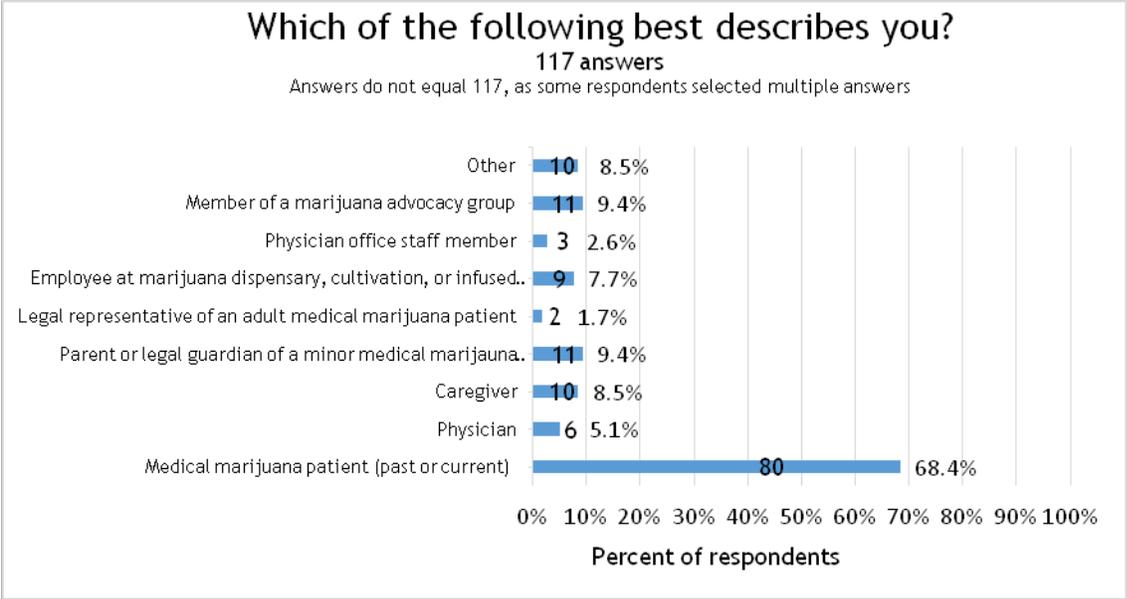
	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves 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.

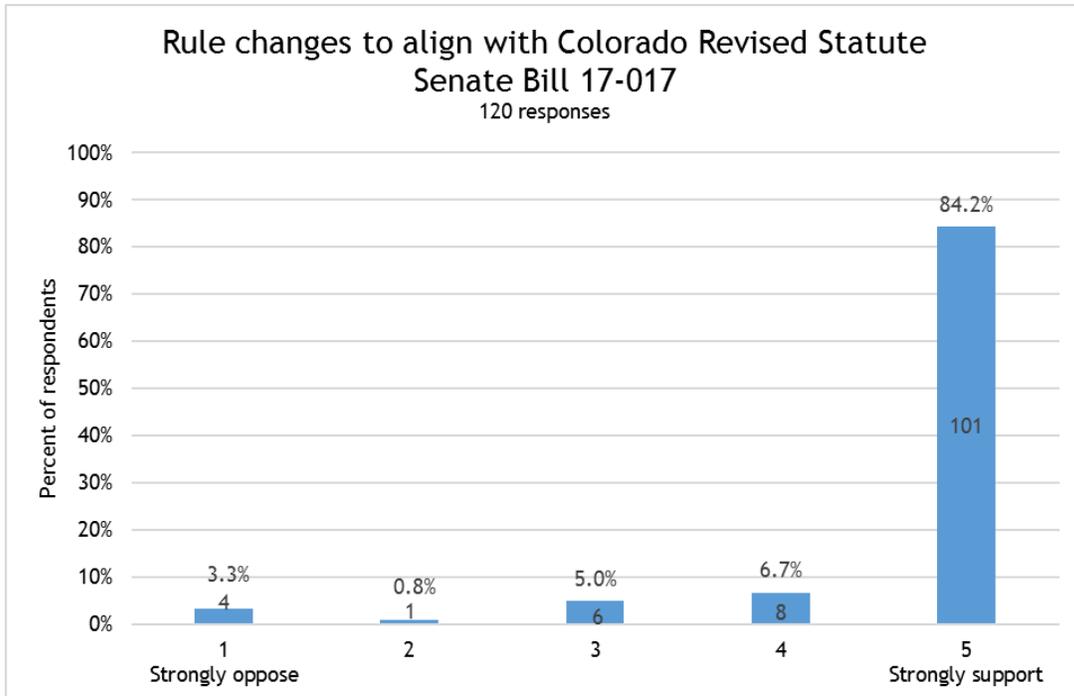
Stakeholder Survey results

Summary:

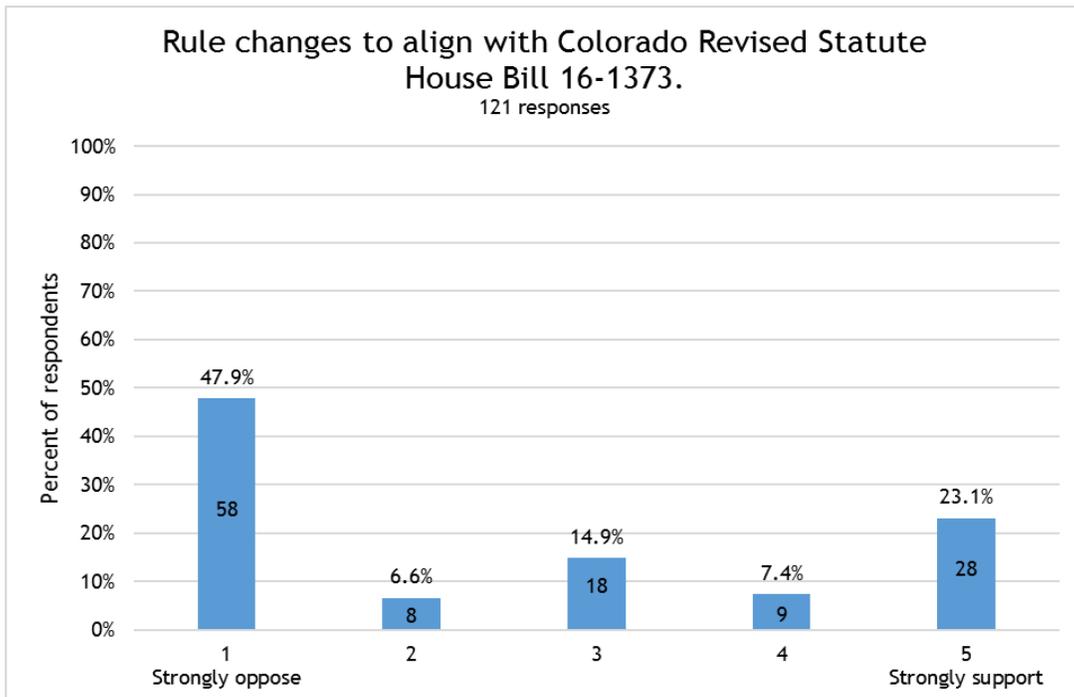
- Respondents were asked to rate the degree to which they oppose or support each rule change.
- 125 individuals responded.
- Not all respondents answered each question.
- Each chart includes the percent and total number of individuals that responded to the question.



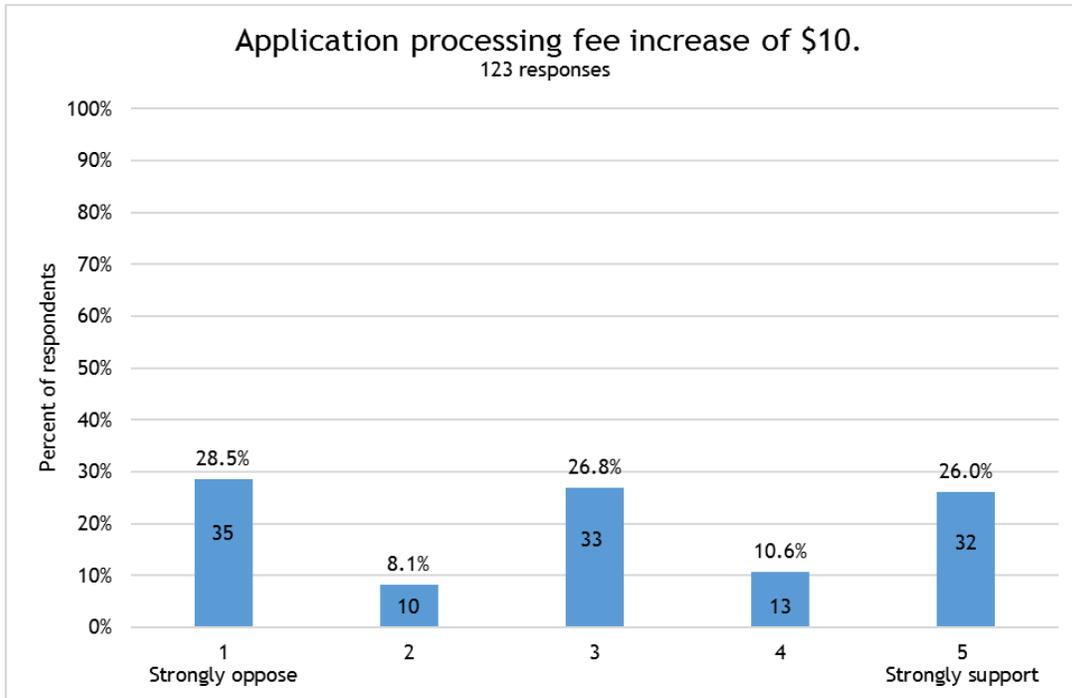
The majority of respondents were past or current medical marijuana patients.



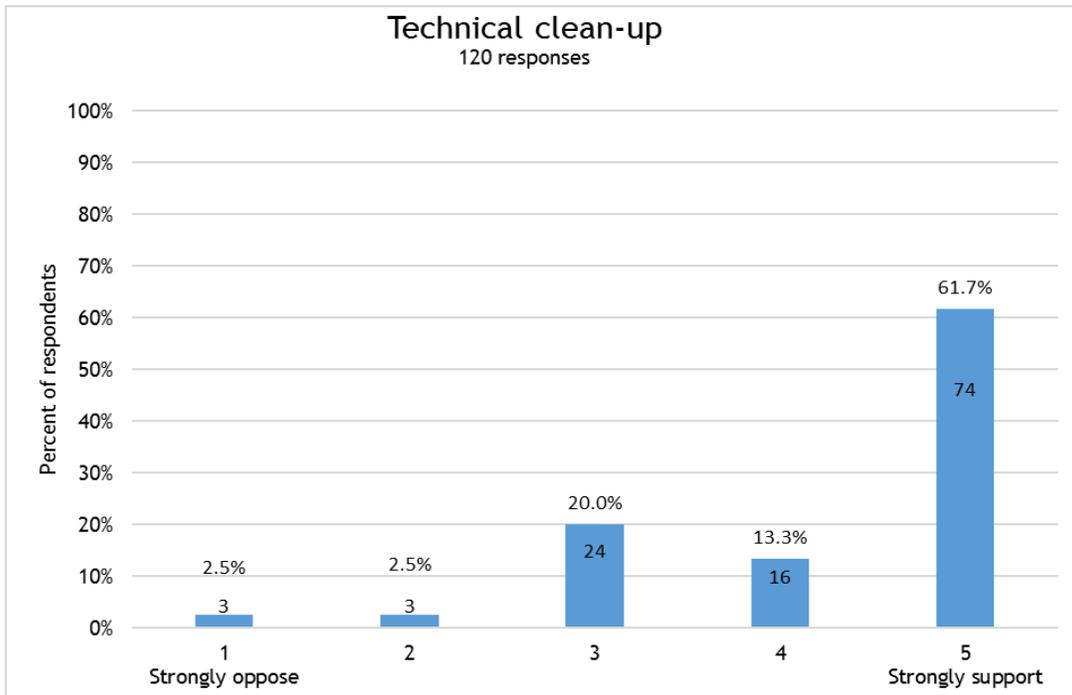
Most respondents strongly support rule changes to align with Senate Bill 17- 017.



Most respondents opposed the proposed changes to align with House Bill 16-1373. To address this stakeholder feedback, the Department is proposing the removal of Regulation 9.J.4. and Regulation 12.C.4 under the basis that the Medical Marijuana Registry does not have a role in school settings.



Responses regarding an increased application processing fee were split. Without approval for this fee increase, the Medical Marijuana Registry program will not be able to sustain the direct and indirect costs of maintaining the program.



Most respondents strongly support technical clean-up changes.

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.]*

6

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 *****

27 6. A copy of a secure and verifiable identity document, in compliance with the Secure and
28 Verifiable Document Act, C.R.S. §24-72.1-101 et seq., C.R.S. for the patient and primary
29 care-giver, if any is designated.

30 *****

31 C. Definitions

32 *****

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

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

- 39 5. “Patient” means a person who has a debilitating medical condition or disabling medical
40 condition, § 25-1.5-106(2)(d.3), C.R.S.
- 41 6. “Primary care-giver” or “primary caregiver” means a person other than the patient and the
42 patient’s physician, who is eighteen years of age or older and has significant
43 responsibility for managing the well-being of a patient who has a debilitating or disabling
44 medical condition. A primary caregiver may have one or more of the following
45 relationships:
- 46 a. A parent of a child as described by ~~section-Section~~ (6) (e) of ~~section-Section~~ 14
47 of ~~article-Article xviii XVIII~~ of the Colorado Constitution ~~-or § 25-1.5-106.5, C.R.S.~~,
48 and anyone who assists that parent with caregiver responsibilities, including
49 cultivation and transportation;
- 50 b. An advising caregiver who advises a patient on which medical marijuana
51 products to use and how to dose them and does not possess, provide, cultivate,
52 or transport marijuana on behalf of the patient;
- 53 c. A transporting caregiver who purchases and transports marijuana to a patient
54 who is homebound; or
- 55 d. A cultivating caregiver who grows marijuana for a patient.

56 ~~6-7~~

57 *****

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

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

63 *****

64 3. Written documentation from the applicant’s physician that the applicant has been
65 diagnosed with a debilitating medical condition as defined in ~~regulation-Regulation six-6~~
66 or a disabling medical condition as defined by § 25-1.5-106(2)(a.7), C.R.S., and the
67 physician’s conclusion that the applicant might benefit from the medical use of marijuana;

68 *****

69 B. In order for a minor applicant to be placed in the registry and to receive a registry identification
70 card, the minor applicant must reside in Colorado and a parent residing in Colorado must consent
71 in writing to serve as the minor applicant’s primary care-giver. Such parent must complete an
72 application ~~form~~ supplied by the department, and have such application signed and include fee
73 payment. The parent of the minor applicant must provide the following information with the
74 application:

- 75 1. The applicant’s name, address, date of birth, and social security number;
- 76 2. a. For minor patients with a debilitating medical condition, written
77 documentation from two of the applicant’s physicians that the applicant has been
78 diagnosed with a debilitating medical condition as defined in ~~regulation~~

79 Regulation six-6 and each physician's conclusion that the applicant might benefit
80 from the medical use of marijuana, or

81 b. For minor patients with a disabling medical condition, written documentation
82 from:

83 i. Two physicians, one of whom must be a board-certified pediatrician, a
84 board-certified family physician, or a board-certified child and adolescent
85 psychiatrist who attests that he or she is part of the patient's primary care
86 provider team, have diagnosed the patient as having a disabling medical
87 condition, and

88 ii. The physician that explained the risks and benefits of medical use of
89 marijuana pursuant to subparagraph 5 below, has concluded that the
90 patient might benefit from the medical use of marijuana;

91
92 *****
93

94 D. ~~A patient may change his or her primary care-giver with the department no more than once per~~
95 ~~month.~~ A patient may change his or her primary care-giver by submitting such information, ~~on the~~
96 ~~form and~~ in the manner ~~as directed~~ determined by the department, within ten days of the change
97 occurring. The department does not process patient requests to change his or her designated
98 medical marijuana center; a patient wishing to change his or her designated medical marijuana
99 center should reference the requirements established by the department of revenue's marijuana
100 enforcement division.

101 E. Rejected applications. Rejected applications shall not be considered pending applications, and
102 shall not be subject to the requirement in the Constitution or § 25-1.5-106.5, C.R.S. that
103 applications be deemed approved after thirty-five days. The department may reject as incomplete
104 any patient application for any of the following reasons:

- 105 1. If information contained in the application is illegible or missing;
- 106 2. The physician(s) is/are not eligible to recommend the use of marijuana.
- 107 3. An applicant shall have (60) days from the date the department notifies the applicant of
108 ~~mails~~ the rejected application to make corrections and resubmit the application.

109 *****

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

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

118 *****

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

121 A. The department shall verify medical information contained in the patient's application within thirty
122 days of receiving the application. Verification of medical information shall consist of determining
123 that there is documentation stating the applicant has a current diagnosis with a debilitating or
124 disabling medical condition as defined in ~~regulation-Regulation six6~~, by a physician who has a
125 current active, unrestricted and unconditioned license as defined in Regulation 8 to practice
126 medicine issued by the State of Colorado, which license is in good standing, and who has a bona
127 fide physician patient relationship with the patient as defined in regulation eight.

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

- 131 i) The patient's name, address, date of birth, and social security number;
- 132 ii) That the patient's name has been certified to the department as a person with a
133 debilitating or disabling medical condition, whereby the person may address such
134 condition with the medical use of marijuana;

135 *****

136 C. Except for minor applicants with a debilitating medical condition, where the department fails within
137 thirty-five days of receipt of application to issue a registry identification card or fails to issue verbal
138 or written notice of denial of such application, the patient's application for such card will be
139 deemed to have been approved. "Receipt" shall be deemed to have occurred upon delivery to the
140 department or deposit in the United States mail. No application shall be deemed received prior to
141 June 1, 2001.

142 *****

143 E. In addition to any other penalties provided by law, the department shall revoke for a period of one
144 year the registry identification card of any patient found to have willfully violated the provisions of
145 Section 14 of Amendment 20 of the Colorado Constitution or ~~the implementing legislation of~~
146 Section 14§ 25-1.5-106, C.R.S.

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

148 A. When there has been a change in the name, address, physician or primary care-giver of a patient
149 who has been issued a registry identification card, that patient must notify the department within
150 ten days by submitting ~~a completed Change of Address or Care-giver form as the necessary~~
151 information in the manner prescribed by the Department. A patient who has not designated a
152 primary care-giver at the time of application to the department may do so in writing at any time
153 during the effective period of the registry identification card, and the primary care-giver may act in
154 this capacity after such designation. The Department shall not issue a new registry identification
155 card to the patient on the sole basis of a new or change of primary care-giver.

156 B. A patient who no longer has a debilitating medical condition as defined in ~~regulation-Regulation~~
157 ~~six-6 or a disabling medical condition as defined by § 25-1.5-106 (2)(a.7), C.R.S. or a~~ shall return
158 his registry identification card to the department within twenty-four hours of receiving such
159 information by his or her physician.

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

161 A. Authorized employees of state or local law enforcement agencies shall be granted access to the
162 information contained within the department's registry only for the purpose of verifying that an
163 individual who has presented a registry identification card to a state or local law enforcement
164 official is lawfully in possession of such card. The department shall report to authorized state or

165 local law enforcement officials whether a patient's registry identification card has been suspended
166 because the patient no longer has a debilitating or disabling medical condition.
167

168 B. Authorized employees of state or local law enforcement agencies shall immediately notify the
169 department when any person in possession of a registry identification card has been determined
170 by a court of law to have willfully violated the provisions of this ~~section~~ Section 14 of Article XVIII
171 of the Colorado constitution or § 25-1.5-106.5, C.R.S. ~~its implementing legislation~~, or has pled
172 guilty to such offense.
173

174 *****

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

177 *****
178

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

181 *****
182
183

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

186 A. Application fee. Effective ~~May 15, 2018~~ February 1, 2014, the ~~De~~partment shall collect twenty-
187 five fifteen dollars from each applicant at the time of application to pay for the direct and indirect
188 costs to administer the medical use of marijuana program, unless the applicant meets the criteria
189 set forth in section (b) of this Regulation (7) establishing indigence. Such fee shall not be
190 refundable to the applicant if the application is denied or revoked or if the patient no longer has a
191 debilitating or disabling medical condition. The amount of the fee shall be evaluated annually by
192 the department to ensure compliance with the applicable statutes and the fee meets the actual
193 Medical Marijuana Registry expenses. The department shall propose modifications to the board,
194 as appropriate. If the patient provides updated information at any time during the effective period
195 of the registry identification card, the department shall not charge a fee to modify the registry
196 information concerning the patient.

197 *****

198 C. Notification of indigent status. Individuals who meet the indigence standard after they have been
199 approved for the medical marijuana registry may ~~complete a form, to be~~ provide the necessary
200 information in the manner determined by the department, notifying the department of their status
201 and supplying a copy of the applicant's state tax return certified by the department of revenue that
202 confirms that the applicant's income does not exceed one hundred eighty-five percent of the
203 federal poverty line, adjusted for family size. Upon receipt and confirmation of the information, the
204 department shall issue a new medical marijuana registry card for the remaining term of the
205 current card noting said indigent status for tax exemption purposes.

206

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

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

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

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

218 i. The physician holds a doctor of medicine or doctor of osteopathic
219 medicine degree from an accredited medical school.

220 ii. The physician holds a valid license to practice medicine in Colorado that
221 does not contain a restriction or condition that prohibits the
222 recommendation of medical marijuana or for a license issued prior to
223 July 1, 2011, a valid, unrestricted and unconditioned; and

224 iii. The physician has a valid and unrestricted United States Department of
225 Justice federal drug enforcement administration controlled substances
226 registration.

227 2. **Bona fide physician patient relationship.** A physician who meets the requirements in
228 subsection A.1 of this Regulation 8 and who has a bona fide physician-patient
229 relationship with a particular patient may certify to the state health agency that the patient
230 has a debilitating or disabling medical condition and that the patient may benefit from the
231 use of medical marijuana. If the physician certifies that the patient would benefit from the
232 use of medical marijuana based on a chronic or debilitating disease or medical condition,
233 or a disabling medical condition, the physician shall specify the chronic or debilitating
234 disease or medical condition, or disabling medical condition, and, if known, the cause or
235 source of the chronic or debilitating disease or medical condition, or disabling medical
236 condition.

237 a. "Bona fide physician-patient relationship", for purposes of the medical marijuana
238 program, means:

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

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

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

250 *****

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

252 *****

253 c. Examine a patient for purposes of diagnosing a debilitating or disabling medical
254 condition at a location where medical marijuana is sold or distributed; or

255 d. Hold an economic interest in an enterprise that provides or distributes medical
256 marijuana if the physician certifies the debilitating or disabling medical condition
257 of a patient for participation in the medical marijuana program.

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

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

266 *****

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

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

271 2. Summary suspension of the physician's ability to certify a debilitating or disabling medical
272 condition or recommend medical marijuana for an applicant to the medical marijuana
273 registry when the department reasonably and objectively believes that a physician has
274 deliberately and willfully violated ~~section~~ Section 14 of ~~article~~ Article xviii ~~XVIII~~ of the state
275 Colorado ~~C~~onstitution or § 25-1.5-106, C.R.S. and the public health, safety and welfare
276 imperatively requires emergency action.

277 *****

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

279 *****

280 C. An existing primary care-giver may indicate to the department, at the time of registration, ~~on a~~
281 ~~form to be developed in the manner determined~~ by the department if the primary care-giver is
282 available to serve more patients. An individual who is not a registered primary care-giver, but who
283 would like to become one may submit contact information to the registry. The primary care-giver
284 or prospective primary care-giver shall waive confidentiality to allow release of contact
285 information to physicians or registered patients only. The department may provide the information
286 but shall not endorse or vouch for any primary care-giver or prospective primary care-giver.

287 *****

288 J. A primary care-giver shall not:

289 *****

290 ~~4. Possess medical marijuana or otherwise engage in the use of medical marijuana in or on~~
291 ~~the grounds of a school or in a school bus except when the possession or use occurs in~~
292 ~~accordance with a school district board policy established pursuant to § 22-1-119.3,~~
293 ~~C.R.S.;~~

- 294 ~~54.~~ Engage in the use of medical marijuana while:
- 295 a. In a correctional facility or a community corrections facility;
- 296 b. Subject to a sentence to incarceration; or c. In a vehicle, aircraft, or motorboat;
- 297 ~~65.~~ Operate, navigate, or be in actual physical control of any vehicle, aircraft, or motorboat
- 298 while under the influence of medical marijuana; or
- 299 ~~76.~~ Provide medical marijuana if the patient does not have a debilitating or disabling medical
- 300 condition as diagnosed by the person's physician in the course of a bona fide physician-
- 301 patient relationship and for which the physician has recommended the use of medical
- 302 marijuana.

303 *****

- 304 L. A primary care-giver shall have significant responsibility for managing the well-being of a patient
- 305 with a debilitating or disabling medical condition.

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

307 *****

- 308 B. Waiver applications shall be submitted to the department ~~on the form and~~ in the manner required
- 309 by the department.

310 *****

311 **Regulation 11: Waiver for primary care-givers to deliver medical marijuana products from a**

312 **medical marijuana center.**

- 313 A. If the physician recommending the marijuana checks on the physician certification recommending
- 314 ~~form~~ that the patient is homebound, a waiver will be granted allowing a designated primary care-
- 315 giver to transport marijuana from a medical marijuana center to the patient.

316 *****

317 **Regulation 12: Patient Responsibilities.**

- 318 A. A patient who is using the services of a care-giver shall provide his/her care-giver with a copy of
- 319 his/her application, physician certification and registration card, once issued. A copy of the
- 320 patient's application and registration card shall be in the primary care-giver's possession at all
- 321 times that the primary care-giver is in possession of marijuana. The patient may obscure or
- 322 redact the mailing address and social security number on the copy of the application or
- 323 registration card given to the primary care-giver.

- 324 B. When a patient changes his or her primary care-giver, the patient shall submit notice of the
- 325 change ~~on the form and~~ in the manner as directed by the department. The patient shall notify
- 326 ~~their give a copy of the submitted form to the~~ primary care-giver. The patient may obscure or
- 327 redact the mailing address and social security number on the copy of the ~~form information~~ given
- 328 to the primary care-giver.

- 329 C. A patient shall not:

330 *****

331 ~~4. Possess medical marijuana or otherwise engage in the use of medical marijuana in or on~~
332 ~~the grounds of a school or in a school bus except when the possession or use occurs in~~
333 ~~accordance with a school district board policy established pursuant to § 22-1-119.3,~~
334 ~~C.R.S.;~~

335 *****

336 7. Use medical marijuana if the patient does not have a debilitating or disabling medical
337 condition as diagnosed by the person's physician in the course of a bona fide physician-
338 patient relationship and for which the physician has recommended the use of medical
339 marijuana.

340 D. A patient who no longer has a debilitating or disabling medical condition shall return his or her
341 registry identification card to the department within twenty-four hours of receiving such diagnosis
342 by his or her physician.

343 E. A patient shall notify the department if convicted of a criminal offense under Article 18 of title
344 Title 18, C.R.S., sentenced or ordered by a court to drug or substance abuse treatment, or
345 sentenced to the division of youth corrections. The patient shall be subject to immediate renewal
346 of his/her registry identification card. Such patient may only reapply with a new physician
347 recommendation from a physician with whom the patient has a bona fide relationship.

348 *****

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

350 A. The department shall require that a fee be paid to the department for any subpoena served. The
351 fee shall be paid at the time of service of any subpoena upon the department plus a fee for meals
352 and mileage at the rate prescribed for state officers and employees in Section § 24-9-104, C.R.S.
353 for each mile actually and necessarily traveled in going to and ~~returning~~ returning from the place
354 named in the subpoena. If the person named in the subpoena is required to attend the place
355 named in the subpoena for more than one day, there shall be paid, in advance, a sum to be
356 established by the department for each day of attendance to cover the expenses of the person
357 named in the subpoena.

358 *****