COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Natalie Riggins, Program Manager, Center for Health and Environmental Data

Through: Chris Wells, Division Director, Center for Health and Environmental Data *CSW*

Date: December 15, 2021

Subject: Emergency Rulemaking concerning 5 CCR 1006-2, Medical Use of Marijuana

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The Medical Marijuana Registry (MMR) is proposing modifications to the Medical Use of Marijuana regulations to align with House Bill 21-1317, which was passed in the 2021 legislative session. The vast majority of the changes must occur for the rule to remain in alignment with statute.

Overview of the changes

Regulation 1 – proposed changes align the definition of bona-fide physician-patient relationship with the language in the bill, include a technical edit to more accurately capture physician requirements outlined in statute, and add the definition of "written documentation" which is also found in Colorado Constitution.

Regulation 2 - proposed changes align with new requirements for provider certifications and application requirements for patients age 18-20.

Regulation 8 - proposed changes align with bill language regarding physician record keeping and fees for extended plant counts.

The Department is requesting that these rules be effective Jan. 1, 2022.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to 5 CCR 1006-2

Basis and Purpose.

The majority of the revisions proposed to Regulation 1 are necessary to ensure the rule language remains in alignment with House Bill 21-1317, though there is one additional adjustment that was made based on feedback from the Office of Legal and Legislative Services (OLLS) after MMR's last rulemaking in 2019. Proposed changes to Regulations 2 and 8 are necessary to ensure that the rule language remains in alignment House Bill 21-1317 which becomes fully effective on Jan. 1, 2022. A summary of the changes by regulation follow.

Regulation 1

- Proposed changes to the definition of "bona fide physician-patient relationship" in Regulation 1.C.2.a align the rule language with the changes in statute. House Bill 21-1317 updated the definition of "bona fide physician-patient relationship" to clarify that:
    - An exam for a medical marijuana recommendation must be done in person.
    - The physician's assessment of the patient's medical history must include determining whether the patient has a medical or mental health issue that could be exacerbated by the use of medical marijuana.
    - If the physician is not the patient's primary care provider, the physician shall review the existing records of a diagnosing physician or licensed mental health provider.

- The proposed change in Regulation 1.C.2.b is a technical edit to more accurately capture the physician requirements that are established in statute. This proposed change was based on feedback from the Office of Legislative and Legal Services (OLLS) after MMR's last rulemaking review in 2019. During the 2019 rulemaking, stakeholder testimony indicated that stakeholders wanted the rule to require physicians to document that they explained the possible risks and benefits of using medical marijuana. In an effort to honor stakeholder feedback, the Department incorporated the feedback into the rule. The Department is proposing the current changes to ensure alignment with statute while honoring feedback from OLLS and from stakeholders during the 2019 rulemaking.

- The definition of "written documentation" in Regulation 1.C.11 was added to enhance readability of the rule. This definition is in alignment with the definition found in Colorado Constitution.

Regulation 2

- House Bill 21-1317 requires physicians to include additional information when they certify to the state health agency that a patient has a debilitating or disabling medical condition and that the patient may benefit from medical marijuana. The bill also specifies that physicians are to give a patient a copy of the certification. The proposed changes to Regulation 2.A.3 align with the newly required information. Changes to Regulation 2.B.2 clarify that physicians are also required to include the information on the certification when a patient is under age 18.

- Additionally, House Bill 21-1317 established new application requirements for applicants aged 18-20 years old. Proposed changes to Regulation 2.A.3.b incorporate the new requirements by referring the reader to statute.
- Patients that have a valid registry identification card prior to Jan. 1, 2022 will maintain current their registration. A new physician certification will be required upon renewal for any registration that expires after Jan. 1, 2022.

Regulation 8

- House Bill 21-1317 clarifies that as part of the record keeping system physicians must:
  - Keep a copy of the certifications that they write when authorizing a patient to use medical marijuana.
  - Respond to a treating physician's request for medical records in order to treat a patient. This must be done with the patient's permission.

  Proposed language changes to Regulation 8.A.3 aligns with these changes while also recognizing that physicians must keep records in accordance with all other applicable state and federal laws.

- House Bill 21-1317 also states that physicians may not c an additional fee for extended plant counts. Proposed modifications to Regulation 8.A.4.e align with the change.

MMR will be working towards compliance with these new requirements as a result of House Bill 21-1317 and will continue to share information with stakeholders about how changes may affect Registry processes.

Emergency Rulemaking Finding and Justification:
An emergency rulemaking, which waives the initial Administrative Procedure Act noticing requirements, is necessary to comply with state law. Emergency rulemaking is authorized pursuant to section 24-4-103(6), C.R.S. House Bill 21-1317 has a January 1, 2022 effective date.

The Department is requesting that this emergency rule shall become effective on January 1, 2022. It will be effective for no more than 120 days after its adoption unless made permanent through a rulemaking that satisfies the Administrative Act noticing requirements.

Specific Statutory Authority.

Statutes that require or authorize rulemaking: Colorado Constitution, Article XVIII, Section 14 and § 25-1.5-106, C.R.S.

Is this rulemaking due to a change in state statute?

___X___ Yes, the bill number is House Bill 21-1317. Rules are ___ authorized
__X_ required.

_____ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

_____ Yes ___ URL

___X___ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

____X__ No

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

_X__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
For Amendments to 5 CCR 1006-2

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

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Current and prospective medical marijuana registry patients aged 0-17 and 21 and over	100,000	C, B
Current and prospective medical marijuana registry patients age 18-20	5,000	C, B
Health care providers that recommend medical marijuana	500	C, B

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

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.

Economic outcomes
Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

All current and prospective medical marijuana registry patients
The economic outcomes are unknown. MMR received feedback from a stakeholder stating that a poll they conducted of recommending providers showed that half of their poll respondents will stop recommending medical marijuana if the rule changes are adopted. The stakeholder expressed concern that if a large number of recommending providers were to stop recommending medical marijuana as part of their practice, it could lead to patients experiencing higher prices for medical marijuana related health appointments. However, the Department has only heard form one practitioner independent of the poll, and is unable to determine if such an increase in the price for appointments would occur,

or how much such an increase would be. The Department is obligated to align the rule with statute.

Medical marijuana registry current and prospective patients age 18-20
House Bill 21-1317 requires first-time applicants in this age group to see two physicians from two different medical practices and to submit two certifications from different physicians. Homebound patients that did not have a registry card before they were 18 still need two certifications from different physicians, but the physicians do not need to be from different practices. Patients in this group will incur the fees charged by both medical providers. The Registry does not oversee or have access to the fees that medical providers charge patients for medical marijuana examinations.

Applicants in this age group that had a registry identification card before they turned 18 do not have to submit two certifications from two providers at different medical practices, so may not experience the same economic impact as first-time patients in the 18-20-year-old age group.

Health care providers that recommend medical marijuana
Some of the proposed changes add additional details to how physicians and health care providers should maintain records and write certifications. The economic impact of these changes to health providers is unknown.

Non-economic outcomes
Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

All current and prospective medical marijuana registry patients
The non-economic outcomes are unknown. MMR received feedback from a stakeholder stating that a poll they conducted of recommending providers showed that half of respondents will stop recommending medical marijuana if the rule changes are adopted. The stakeholder expressed concern that if a large number of recommending providers were to stop recommending medical marijuana as part of their practice, patients may have a harder time accessing medical care from a provider who recommends medical marijuana. However, the Department has only heard from one practitioner independent the poll and is unable to determine the extent to which the changes could affect access to care. Additionally, the Department is obligated to align the rule with statute.

Current and prospective medical marijuana registry patients age 18-20
House Bill 21-1317 requires first-time applicants in this age group to see two physicians from two different medical practices and to submit two certifications from physicians at different medical practices. It may take these individuals more time and effort to apply for a registry identification card since they will have to visit more than one medical office. Patients that did not have a registry identification card before age 18 and are designated as homebound by their physician still have to submit two certifications from different physicians, but the physicians do not have to be from different practices. They will likely experience some impact as they apply for a registry identification card.

Applicants in this age group that had a registry identification card before they were 18 do not have to submit two certifications, so will not experience the same impact.

Health care providers that recommend medical marijuana
House Bill 21-1317 requires that physicians include more information on provider certifications and outlines more explicit guidance about maintaining medical records. Providers may experience non-economic impacts as they adjust to complying with the changes and new processes.

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

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

MMR is a fee based program that is funded solely by the application processing fee that is collected at the time a patient applies to the registry. Fees are consistently evaluated to ensure that the revenue being generated is sufficient to cover the expenses of administering the MMR program. In 2018 the application processing fee was set at $25, and all revenue generated from the fee is held in the Medical Marijuana Cash Fund.

A breakout of the costs outlined in the Fiscal Note of HB 21-1317 is provided in the table below. MMR is currently pursuing an extension of these appropriations. If granted, spending will begin in FY 2022-2023.

Type of Expenditure	Year 1	Year 2
Personal Services for the 2.1 additional staff needed for updates to Certification form, Stakeholder engagement, provider training, Board of Health Rule-making	$110,935	$34,306
Operating Expenses for contracting with current system vendor to update MMRS, capital outlay for 2.1 additional staff	$165,235	$1,080
Total	$276,170	$35,386

Anticipated CDPHE Revenues:

House Bill 21-1317 appropriated $165,235 from the Medical Marijuana Program Cash Fund for operating expenses related to MMR including contracting with the current system vendor to update MMRS. The bill also appropriated $110,935 from the Medical Marijuana Program Cash fund for personal services related to the medical marijuana registry, which amount is based on an assumption that the registry will require an additional 2.1 FTE.

The most recent analysis of MMR funds indicates that the current fee of $25 will not generate enough revenue to meet the appropriated fund amounts established in the bill and also cover

the direct and indirect costs of sustaining the program. The Board will be holding a separate hearing on December 15, 2022 for a fee increase related to implementing HB 21-1317.

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

Anticipated Revenues for another state agency:

N/A

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

Along with the costs and benefits discussed above, the proposed revisions:

__X_ Comply with a statutory mandate to promulgate rules.
_X__ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
___ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
_X__ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-

Management Education and Support by collaborating with the Department of Health Care Policy and Financing.

4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.

___ Ensures access to breastfeeding-friendly environments.

5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.

___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.
___ Performs targeted programming to increase immunization rates.
___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).

6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023. _X__ Implements the CDPHE Digital Transformation Plan. _X__ Optimizes processes prior to digitizing them. _X__ Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations
11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment

_X__ Advance CDPHE Division-level strategic priorities.

- Optimize customer experience.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

Failure to incorporate these changes will result in the rule being out of alignment with the statute.

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. Aligning the rule with the soon to be effective House Bill 21-1317 ensures consistent processing and service to Medical Marijuana Registry patients and customers. The proposed revisions provide the most benefit for the least amount of cost and are the minimum necessary or are the most feasible manner to achieve compliance with statute.

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

No other alternatives were considered. Rulemaking is the statutorily required mechanism to implement these changes for the reasons described in the Statement of Basis and Purpose.

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.

All projections are based on continuing revenue and expense data, which are re-assessed and updated on a monthly basis as monthly fund balance and accounting data is updated. Projections, to the extent possible, are updated through the subsequent three years.

STAKEHOLDER ENGAGEMENT
for Amendments to 5 CCR 1006-2

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:

Medical Marijuana Registry Stakeholder groups

- Medical Marijuana Registry Stakeholders (voluntary list serv open to everyone)
- Medical Marijuana Registry Physicians
- Medical Marijuana Registry Caregivers

Stakeholder feedback was collected through an online form beginning in late October, 2021. Along with the online form, stakeholders were invited to provide comments via U.S. mail. MMR staff reviewed each piece of feedback that was submitted.

Information about the emergency rulemaking and about how to submit feedback to the Department has been publicized on the Medical Marijuana Registry website and the program is currently accepting feedback.

Summary of feedback
MMR has gathered feedback about the proposed changes to align with statute. Recently, MMR collected stakeholder feedback for another rulemaking hearing to increase the application processing fee to generate funds to implement House Bill 21-1317. Throughout that process, stakeholders also shared feedback about the implementation of House Bill 21-1317, which is included below. MMR will continue to collect feedback about the proposed changes to align the rule with House Bill 21-1317 leading up to the permanent hearing in February.

Regulation 1
Bona-fide physician-patient relationship

Stakeholders gave feedback about the changes to the bona-fide physician-patient relationship and requested that the changes to the rule do not include the word “must” when discussing how physicians review existing medical records. The proposed changes are able to honor this request by aligning with language from statute, which uses the word “shall” instead of “must” and reads, “If the recommending physician is not the patient’s primary care physician, the recommending physician shall review the existing records of the diagnosing physician or a licensed mental health provider.” These changes are also reflected in the summary to the changes of the regulation in the Statement of Basis and Purpose.

Another stakeholder also stated that should be up to be the physician’s discretion about whether or not medical records need to be obtained. They also expressed that it is not reasonable or fair to expect a physician to be able to make a determination about whether or not the patient has a medical or mental health condition that could be exacerbated by medical marijuana as the full health effects of cannabis are unknown. Stakeholders also raised concerns that the changes due to House Bill 21-1317 redefine a physician’s scope

because it requires that patients 18-20 see two physicians for a medical marijuana recommendation, which it is not consistent with diagnoses for other conditions. While MMR understands and recognizes these concerns, the proposed changes align with statute and the Department is obligated to align rule with law.

Regulation 2

Changes to required information on the provider certification

MMR received feedback opposing the proposed changes that require more information on provider certifications. Feedback expressed concerns that the changes require recommending providers to violate existing laws by writing a prescription for marijuana, which is still a Schedule 1 substance federally. Physicians and medical providers were concerned that this would put them in a position to potentially lose their DEA license or be held liable for the actions of someone who was harmed and found to have medical marijuana in their system or been harmed by a person having medical marijuana in their system.

Stakeholders also expressed opposition to some of the required information, like maximum potency, product, and directions for use because patient tolerance can vary and that the dose can only be determined by trial and error by the patient. Stakeholders suggested that the rule state that physicians should have patients begin with the lowest potency and work their way up as needed or that providers simply recommend that medical marijuana may help the patient with the understanding that patients must discover for themselves which doses, frequencies, and formulations work best for them.

A stakeholder also had concerns that the requirement to provide the patient with a copy of the certification could lead to forgeries of other types of prescriptions, like narcotics, because a patient would have relevant information about the physician such as their DEA number. Further, a stakeholder emphasized that these requirements for physicians and medical marijuana patients are not fair as those that use adult-use marijuana are not held to the same requirements.

While the Department appreciates and understands these concerns, the intent of the proposed changes is to align the rule with state statute so that the Department is in compliance with the law.

Effective date of changes to provider certifications

MMR received feedback requesting that existing patients with a valid registry identification card not be required to obtain a new certification with the newly required information if their card and certification was valid before Jan. 1, 2022. MMR and the Department will be able to accommodate this. Patients that have a valid registry identification card prior to Jan. 1, 2022 will be able to maintain their registration and will not have to submit a new physician certification for their current registration period.

Requirements of patients 18-20 to submit two provider certifications with their applications under House Bill 21-1317

Feedback raised concerns that this would disproportionally affect low-income and uninsured individuals since it would require a higher cost to see their medical providers at multiple appointments. Stakeholders also expressed that more individuals may turn to the black market to get marijuana to treat their conditions rather than seeking medical care, which could result in negative health outcomes and higher rates of black market marijuana sales.

While MMR understands and appreciates these concerns, the Department is obligated to align rule with statute.

Regulation 8

Charging additional fees for extended plant counts

MMR received feedback requesting that the language prohibiting physicians from charging an additional fee for extended plant counts be removed. Stakeholders explained that recommending providers must be able to change an extra fee for the extra time and administrative burden that is associated with recommending extended plant counts. Additionally, stakeholders emphasized that not charging additional fees for extended plant counts will incentivize more patients to request extended plant counts, which will take providers more time to determine whether or not an extended plant count is truly needed.

While MMR recognizes that there may be additional administrative procedures associated with recommending extended plant counts, the Department must align rule with statute.

Economic and non-economic outcomes

MMR received feedback suggesting that some health care providers would stop recommending medical marijuana as a result of these changes, which could affect all patients' ability to access care as well as raise costs for patients. This information was discussed in the Regulatory Analysis.

Other concerns

General concerns about House Bill 21-1317

Stakeholders also expressed a general opposition to the implementation of House Bill 21-1317 and shared concerns about the bill not supporting patients and making it more difficult for some patients to receive a registry identification card and get access to their medication. Further, stakeholders raised concerns that the changes would lead recommending medical providers to stop recommending so as not to risk losing their DEA or medical licenses, and that providers who continue to recommend medical marijuana may not be aware of the risks that they take on by recommending medical marijuana. Some stakeholders expressed that implementation of House Bill 21-1317 will lead to the destruction of the Colorado Medical Marijuana Registry Program, and one stakeholder gave feedback that a survey they conducted showed responses opposing the bill. Again, while the Department recognizes the concerns, it must comply with statute and implement House Bill 21-1317 as required by law.

Extended plant counts

A stakeholder requested more specific guidance and criteria for determining when a patient should qualify for an extended plant count. MMR does not have the authority to oversee medical practice or determine medical necessity and does not provide guidance on physician practices such as what may qualify a patient for an extended plant count.

Daily purchase limits

MMR also received feedback about the daily purchase limits that are set in House Bill 21-1317. Stakeholders expressed concerns that the limits would lead to hardship and limited access to medicine for patients as well as lead to more underground and black market sales of medical marijuana. While the Department understands this concern, it is outside the scope of the rulemaking and medical marijuana sales are regulated by the Marijuana Enforcement Division at the Colorado Department of Revenue.

Feedback also requested that patients be able to use the purchase limits that are associated with any physician certifications issued prior to Jan. 1, 2022. While MMR recognizes this concern, it is outside the scope of the Department and the rulemaking as the Marijuana Enforcement Division at the Colorado Department of Revenue has authority over sales of medical marijuana products.

Feedback about additional rulemakings

MMR has also been collecting feedback about a proposed application processing fee increase. Throughout the process of collecting feedback about the changes to align with statute, the Department received additional feedback about the fee increase, which was incorporated to the documents relevant to the proposal for the fee increase.

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).

__X__ Not applicable. This is an Emergency Rulemaking. If adopted, notification will occur if the Board of Health sets a hearing for a permanent 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 the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

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

Select all that apply.

	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:_____ _____

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Center for Health and Environmental Data

MEDICAL USE OF MARIJUANA

5 CCR 1006-2

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

Adopted by the Board of Health on ~~September~~ December ~~18~~15, 202~~1~~9, effective ~~November~~ January 1, ~~14~~, 202~~2~~19.

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

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C. Definitions

1. "Adult applicant" is defined as a patient eighteen years of age or older.

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

   a. A physician and a patient have a treatment or counseling relationship, in the course of which the physician has completed a full in-person assessment of the patient's medical history, including an assessment of the patient's medical and mental health history to determine whether the patient has a medical or mental health issue that could be exacerbated by the use of medical marijuana and reviewing a previous diagnosis for a debilitating or disabling medical condition, and current medical condition, including an appropriate personal physical examination~~. "Appropriate personal physical examination" may not be performed by remote means, including telemedicine;~~ If the physician is not the patient's primary care physician, the recommending physician shall review the existing records of the diagnosing physician or licensed mental health provider. This does not require a mental health examination prior to making a recommendation per requirements established in § 25-1.5-106 C.R.S.

   b. The physician has consulted with the patient and if the patient is a minor, with the patient's parents, with respect to the patient's debilitating or disabling medical condition and has explained the possible risks and benefits of use of medical marijuana to the patient, and each of the minor patient's parents residing in Colorado, before the patient applies for a registry identification card. Documentation of the consultation shall be done in accordance with all applicable state and federal laws and regulations~~, and the physician has documented the consultation and explanation in the physician's records~~; and

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

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11. "Written documentation" means a statement signed by a patient's physician or copies of the patient's pertinent medical records as defined in Section 14 of Article XVIII of the Colorado Constitution.

Regulation 2: Application for a registry identification card

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

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

2. At the time of application, the patient will indicate whether he or she will utilize a primary care-giver or a medical marijuana center. Minor patients must have a primary care-giver on record. Patients who are designated by their physician as homebound may request a waiver to list both a primary care-giver and a medical marijuana center. If the primary care-giver is not growing medical marijuana for the patient, the patient may designate a medical marijuana center to grow his/her marijuana plants.

   a. If a care-giver is selected on the application, the patient will identify the care-giver's name and address. This information will be entered into the patient's record and reflected on the registration card.

   b. If a medical marijuana center is selected on the application, the patient's record will reflect the patient has designated a medical marijuana center to grow his/her marijuana. Specific medical marijuana center information will not be reflected on the registration card nor in the patient record.

3. Written documentation from the applicant's physician that the applicant has been diagnosed with a debilitating medical condition as defined in Regulation 6 or a disabling medical condition as defined at § 25-1.5-106(2)(a.7), C.R.S., and the physician's conclusion that the applicant might benefit from the medical use of marijuana.~~;~~ The physician shall provide the patient with a copy of the written documentation.

   a. The written documentation must include:

      i. The date of issue and the effective date of the recommendation;

      ii. The patient's name and address;

      iii. The authorizing physician's name, address, and federal Drug Enforcement Agency number;

      iv. The maximum THC potency level of medical marijuana being recommended;

      v. The recommended product, if any;

      vi. The patient's daily authorized quantity if such quantity exceeds the statutorily allowed amount for the patient's age;

      vii. Directions for use; and

      vii. The authorizing physician's signature.

b. In order for a patient eighteen to twenty years of age to be placed on the registry and receive a registry identification card the patient must meet requirements in § 25-1.5-106.(5.5) C.R.S.

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

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

2. a. For minor applicants with a debilitating medical condition, written documentation, as outlined in Regulation 2.A.3.a, from two of the applicant's physicians that the applicant has been diagnosed with a debilitating medical condition as defined in Regulation 6; or,

b. For minor applicants with a disabling medical condition, written documentation, as outlined in Regulation 2.A.3.a., from two physicians that have diagnosed the patient as having a disabling medical condition as defined at § 25-1.5-106(2)(a.7), C.R.S. If the recommending physician is not the patient's primary care physician, the recommending physician shall review the records of a diagnosing physician or a licensed mental health provider acting within his or her scope of practice;

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

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

1. **Colorado license to practice.** The physician shall have a valid, unrestricted Colorado license to practice that is in good standing.

2. **Bona fide physician-patient relationship.** A physician who has a bona fide physician-patient relationship with a particular patient may certify to the state health agency that the patient has a debilitating or disabling medical condition and that the patient may benefit from the use of medical marijuana. If the physician certifies that the patient would benefit from the use of medical marijuana based on a chronic or debilitating disease or medical condition, or a disabling medical condition, the physician shall specify the chronic or debilitating disease or medical condition, or disabling medical condition, and, if known, the cause or source of the chronic or debilitating disease or medical condition, or disabling medical condition.

a. A physician making medical marijuana recommendations for a debilitating or disabling medical condition shall comply with generally accepted standards of

medical practice, the provisions of the medical practice act, § 12-36-101 et seq., C.R.S, and all Colorado Medical Board rules.

b. When making medical marijuana recommendations for a disabling medical condition, if the physician is a dentist or advanced practice practitioner with prescriptive authority, the dentist or advance practice practitioner must act within the scope of his or her practice and hold a valid license in good standing.

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

a. The authorizing physician shall respond to a patient's treating physician's request for medical records with patient's permission.

b. Records shall be kept in accordance with all applicable state and federal laws and regulations.

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

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

b. Offer a discount or any other thing of value to a patient who uses or agrees to use a particular primary caregiver, distributor, or other provider of medical marijuana to procure medical marijuana;

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

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

e. Charge a patient an additional fee to recommend an extended plant count or for a recommendation that is exception to any requirement in § 25-1.5-106, C.R.S. or -Article 10 of Title 44 of the Colorado Revised Statutes.

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