STATE OF COLORADO

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

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Colorado Department
of Public Health
and Environment

To: Members of the Colorado State Board of Health

From: Ron Hyman, Medical Marijuana Registry Director

Through: Dana Erpelding, Division Director DE
Health and Environmental Information and Statistics

Date: July 16, 2014

Subject: **Request for Rule-Making Hearing**
Proposed Amendments to 5 CCR 1006-2, Medical Use of Marijuana, with a request for the rulemaking hearing to occur on September 16, 2014.

The Medical Marijuana Registry (MMR) is proposing rules to fulfill new statutory requirements due to Senate Bill 14-155. In addition, the proposed rules include updates to reflect current terminology, align with Department of Revenue regulations where appropriate, and clarify MMR processes. The proposed changes are outlined below. Along with the summary of changes, the MMR has provided a brief history and overview of the Department of Public Health and Environment and the Department of Revenue roles and responsibilities. This overview is attached to this memo, Attachment A.

A. NEW: REGULATION 14: COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM

The MMR is proposing the necessary rules to fulfill the statutory requirement of Senate Bill 14-155 which creates a medical marijuana research grant program to ascertain the general medical efficacy and appropriate administration of medical marijuana. SB 14-155 requires the Board of Health to promulgate rules delineating the grant process. These rules specify the procedures and timelines by which an entity may apply for program grants; contents of grant applications; criteria for selecting entities to receive grants and determining the amount and duration of the grants, and; reporting requirements for entities that receive grants. The Division drew upon the existing A35 grant program rules and then tailored the rules as needed to implement SB 14-155.

B. MODIFICATIONS TO REGULATION 6: DEBILITATING MEDICAL CONDITIONS AND THE PROCESS FOR ADDING NEW DEBILITATING MEDICAL CONDITIONS

Senate Bill 14-155 requires the development of a Scientific Advisory Council (council) to evaluate research grant proposals and submit recommendations to the State Board of Health for a final determination. Existing Board of Health regulations create an ad hoc medical advisory panel to review petitions for adding a debilitating medical condition to Board of Health rules. The Department is proposing that the council be charged to reviewing petitions to add a debilitating medical condition. This council will be responsible for evaluating research proposals and reviewing

petitions to have medical conditions added to the rules. This will create important feedback, linking medical marijuana research to debilitating conditions petitions and is an efficient use of time for the community-partners willing to support the MMR. The statutory structure of the council draws upon and expands the membership of the ad hoc medical advisory panel. The change from past practice is that there is no longer a petitioner recommended physician that sits on the committee. The petitioner can provide the opinions and research of the physician at the time of filing the petition. A comparison of the committee requirements and a brief biography of the appointed council members is attached to this memo, Attachment B.

Along with aligning the grant and petition processes, the research criteria in the debilitating conditions portion of the rule has been expanded to include both peer-reviewed published studies of randomized controlled studies and well-designed observational studies to establish efficacy and medical necessity. This modification supports the council's ability to incorporate data provided through the above-referenced research grants program.

C. MODIFICATIONS TO REGULATION 2: APPLICATION FOR A REGISTRY IDENTIFICATION CARD

1. Proof of Identity and Residency

The Constitution requires that patients prove residency to obtain a medical marijuana registration card. Residency is not currently defined. Many of the items currently accepted as proof of residency are non-verifiable, as the MMR cannot contact the issuing organization to verify based on confidentiality requirements. By providing a clearer requirement, proof of residency will no longer be one of the top reasons for application rejection. It also enables efficient application processing as staff can confirm the documentation is valid and residency can be established more easily.

The MMR conducted an assessment of residency requirements in other states that have medical marijuana programs as well as a review of other Colorado state agency standards. Based upon the research and upon a recommendation from the Office of the Attorney General, the Department has drawn upon the standards used in the Department of Revenue Retail Marijuana Code (1 CCR 212-2) to establish residency and a waiver process when an individual is unable to do so. This is a change from the documentation that has historically been required by the registry. While there are distinctions between MMR patients, retail marijuana business and consumers, and Medical Marijuana businesses, use of the Department of Revenue standards creates consistency across state agencies and ensures the requirement for MMR patients is reasonable. In addition, the list is short and straight-forward. This will improve patients' ability to quickly and effectively navigate through the application process.

To ensure that there is a mechanism for individuals that may be homebound or have another barrier to obtaining the documentation; the rule includes a waiver process. In developing the non-exhaustive list of waiver criteria the Department relied upon the "Factors Considered When Determining Residency" of individuals in the Department of Revenue Sales, Manufacturing and Dispensing of Medical Marijuana (2 CCR 212-2).

2. Medical Marijuana Center Designations

On average, we receive more than 10,000 change of patient record requests each month. Of these requests, 97% are requests to change medical marijuana center designations. Statute requires that at the time of application, patients indicate whether they will be assigning their plant grow rights to a caregiver or medical marijuana center. While a patient is required to inform the MMR when he/she is changing caregivers, a patient is not required to inform the

MMR when they are changing centers. It is the medical marijuana center's responsibility to report changes in patient count to the Department of Revenue.

No longer recording changes of medical marijuana center in patient records supports patients as it is one less requirement to be met, eliminates a notary cost to MMR patients and keeps the information sharing to the minimum needed for the MMR to execute its statutory obligations. It eliminates a duplication of effort by two state agencies and lets the requirement reside with the Department of Revenue who is empowered to act on the information received. Eliminating this requirement also creates an efficiency for MMR staff which translates to improve card issuance and replacement timelines.

D. MODIFICATIONS TO REGULATION 10: WAIVER FOR PRIMARY CAREGIVERS TO SERVE MORE THAN FIVE PATIENTS

In response the State Auditor's recommendation to strengthen caregiver oversight, we conducted an assessment of caregiver and medical marijuana center data. In addition, we held a Town Hall Meeting on March 28, 2014 to receive public comment on potential changes to caregiver patient limits. The statute charges the registry with ensuring that patients receive quality care from their caregivers. Colorado Revised Statutes 25-1.5-106 requires that the primary caregiver shall have significant responsibility for managing the well-being of a patient with a debilitating condition. The care-giving relationship must be more than providing medical marijuana or medical marijuana paraphernalia. The definition of "significant responsibility for managing the well-being of a patient with a debilitating condition" is in existing Board of Health rules and the Division is not proposing a change to this definition.

As of May 1, 2014, there were 3,622 individuals listed as caregivers representing a total of 4,702 active patients. Of these caregivers 3,104 (99.3%) served five or fewer patients. Of the less than 1% of caregivers who served more than five patients, 18 (81.8%) served 10 or fewer patients. Caregiver Data is attached to this memo, Attachment C. Because caregivers are serving patients with debilitating medical needs, there is concern that sufficient time may not be available for a caregiver to provide care to more than 10 patients in a given time period. In addition, large caregiver grow sites become a public safety concern due to less structured oversight. Based on the data, the requirement that care-givers have significant responsibility for patient care, and the public safety concerns with large grow sites, that department recommends caregivers serve no more than 10 patients at any given time.

At the Town Hall meeting, several patients spoke to limited access due to bans on medical marijuana centers. MMR conducted a comparative review of patients, caregivers and medical marijuana centers to determine limits to access, Attachment D. The vast majority (87%) of patients with caregivers lived within 15 miles of a medical marijuana center. Of those living in areas with county-wide bans, the average distance to a medical marijuana center was 30 miles or farther. As a result, MMR is proposing that the rules add county-wide bans as one of the factors given additional consideration when evaluating a patient limit waiver request.

E. MODIFICATIONS TO REGULATION 12: PATIENT RESPONSIBILITIES

Amendments to Colorado Revised Statute 25-1.5-106 effective July 1, 2012 changed the method by which patients and caregivers may provide proof of registration. As the Registry does not issue caregiver registration cards, patients are required to give their assigned caregiver a copy of their patient application or change of patient record form at the time of submission to the Registry. Upon receipt of their registration card, patients are required to give a copy of the card to their caregiver as proof of the caregiver-patient relationship.

Attachment A: An Overview of Medical Marijuana in Colorado:
Department of Public Health and Environment and the Department of Revenue
Roles and Responsibilities

- The Medical Marijuana Registry was created in 2000 by Amendment 20 which allowed for limited use of medical marijuana. Patients are permitted to use marijuana to alleviate debilitating medical conditions if they have received a physician's recommendation and obtained a registry card from the Medical Marijuana Registry.

- The Colorado Constitution establishes the following debilitating medical conditions as qualifying and individual for medical marijuana use: Cancer, Persistent muscle spasms, Glaucoma, Seizures, HIV or AIDS, Severe nausea, Cachexia, and Severe pain. A physician that has a bona-fide relationship with the patient is required to certify that an individual has a debilitating medical condition as part of the application process.

- The Department of Public Health and Environment was charged with creating and establishing a confidential Medical Marijuana Registry. The Medical Marijuana Registry is funded by a fee on new and renewal applications for the Medical Marijuana Registry card. As of March 2013, about 108,000 patients had valid red cards. Red cards serve as official state documentation that patients have been authorized to obtain, possess, and use marijuana for medical purposes.

- Regulation of caregivers was also assigned to the Department of Public Health and Environment. A primary caregiver must be 18 or older, not be the patient or the patient's physician, and have significant responsibility for managing the well-being of a patient who has a debilitating medical condition. Examples of care-giving include: transportation, housekeeping, meal preparation, shopping, and arranging access to medical care or other services unrelated to medical marijuana. Patients who don't require caregiver service beyond provision of medical marijuana can't designate a primary caregiver.

- Amendment 20 did not contemplate the possible existence of dispensaries but rather focused on requirements for patients to grow and cultivate medical marijuana themselves or obtain it from individuals called primary caregivers (caregivers). In response to the upsurge of dispensaries, the General Assembly passed the Colorado Medical Marijuana Code (House Bill 10-1284) in 2010. That bill established a system of statewide regulations governing the production and sale of marijuana for medical use. Production and sale is under the authority of the Department of Revenue Medical Marijuana Enforcement Division.

- In November 2012, Colorado voters passed Amendment 64, which legalized the use of recreational marijuana for adults who are at least 21 years of age. During the 2013 Legislative Session, the General Assembly enacted legislation related to regulation of Colorado's recreational marijuana industry.

- The Marijuana Enforcement Division (MED) (previously known as the Medical Marijuana Enforcement Division (MMED)) regulates the production and sale of both medical and retail marijuana. This includes regulating medical and recreational marijuana centers, cultivation or growing facilities, and marijuana infused products manufacturing.

Attachment B: Comparison of Board of Health Regulation and Statutory Requirements for Advisory Councils

BOH Ad Hoc Committee	SB 14-155 Requirements	Scientific Advisory Council Members
Executive Director or designee	Chief Medical Officer or his/her designee, Chair of the Council	Executive Director Larry Wolk, MD, MPH
One physician in the appropriate field for the condition requested – recommended by the petitioner		
One physician in the appropriate field for the condition recommended by the department	An ad hoc member with clinical expertise in the medical condition under study	Ken Finn, MD (ad hoc member/pain management)
One physician who recommends medical marijuana in his/her practice	A clinician familiar with the prescription, dosage and administration of medical marijuana	Alan Shackelford, MD
One physician in addiction medicine	A substance abuse specialist	Paula Riggs, MD
	At least one epidemiologist with expertise in designing and conducting large, observational studies and clinical trials.	Tim Byers, MD, MPH
	At least one clinician with expertise in designing and conducting clinical trials.	Jeffrey Galinkin, MD
	A person who represents medical marijuana patient interests	Teri Robnett
	A neurologist	Kristen Park, MD
	A pediatrician	Edward (Ted) Maynard, MD
	A psychiatrist	Doris Gundersen, MD
	An internal medicine physician or other specialist in adult medicine	Joseph Frank, MD, MPH
	A preventive medicine specialist or public health professional	Ken Gershman, MD
	An alternative medicine specialist with expertise in herbal or alternative medicine	Stacy Livingwell, MD

Scientific Advisory Council Members Biographies

1. Tim Byers, MD, MPH (*Epidemiologist with expertise in large epidemiologic studies*)
   Dr. Tim Byers is a Professor of Epidemiology, Associate Dean for Public Health Practice, and Director of the Center for Public Health Practice at the Colorado School of Public Health. He is also Associate Director for Cancer Prevention and Control at the University of Colorado Cancer Center, and is an expert in the role of early detection, diet, and nutrition in the prevention of cancer.

2. Ken Finn, MD (*Ad hoc member/pain management*)
   Dr. Ken Finn is board certified in Physical Medicine and Rehabilitation, Pain Medicine, and Pain Management, and is in private practice at Springs Rehabilitation in Colorado Springs. He was recently elected to the Board of Directors for the American Board of Pain Medicine, and served on the Governor's Task Force on Amendment 64 – Consumer Safety and Social Issues Work Group.

3. Joseph Frank, MD, MPH (*Internal medicine physician*)
   Dr. Joseph Frank is a general internist and health services researcher with the Division of General Internal Medicine at the University of Colorado School of Medicine and the Denver Veterans Affairs Medical Center. His research interests include promoting safe, effective use of opioid pain medications in primary care settings with a focus on the management of comorbid chronic pain and substance use disorders.

4. Jeffrey Galinkin, MD (*Clinician with clinical trials expertise*)
   Dr. Jeffrey Galinkin is Professor of Anesthesiology and Pediatrics at the University of Colorado School of Medicine, as well as Director of Scientific and Medical Affairs at CCPC Clinical Research, an affiliated institution of the University that designs and conducts clinical trials. His core interest is pediatric clinical pain research and clinical trial study design and management.

5. Ken Gershman, MD (*Public health professional*)
   Dr. Ken Gershman is Manager of the Medical Marijuana Research Grant Program at the Colorado Department of Public Health and Environment (CDPHE). He has worked as a public health practitioner at CDPHE for 22 years in the areas of communicable disease control and chronic disease prevention, including managing the Cancer, Cardiovascular Disease, and Chronic Pulmonary Disease (CCPD) Amendment 35 grant program.

6. Doris Gundersen, MD (Psychiatrist with PTSD expertise)
   Dr. Doris Gundersen is a psychiatrist who serves as medical director of the Colorado Physician Health Program, as well as maintains a private practice in Denver. She also has a clinical faculty appointment at the University of Colorado School of Medicine. Dr. Gundersen has treated patients with PTSD through previous work at the VA Hospital and though her private practice.

7. Kennon Heard, MD (*Medical toxicologist*)
   Dr. Kennon Heard is a medical toxicologist at the University of Colorado Hospital Emergency Department. He is the Medical Toxicology Fellowship Director at the Rocky Mountain Poison and Drug Center, and Section Chief of Medical Toxicology at the University of Colorado School of Medicine, where he is also an Associate Professor of Emergency Medicine and Medicine.

8. Stacy Livingwell, MD (*Alternative medicine specialist*)
   Dr. Stacy Livingwell is a holistic family practitioner in Boulder who integrates holistic wellness with traditional medicine, by combining nutrition and movement therapies with mind-body medicine. She specializes in women's health, addiction treatment, chronic pain management, and obesity/weight management. She recommends medical marijuana for some patients.

9. Edward (Ted) Maynard, MD (*Pediatrician*)
   Dr. Ted Maynard is a pediatrician in private practice with Iron Horse Pediatrics in Colorado Springs where he and his colleague have cared for a number of patients whose families have chosen to treat them with Charlotte's Web Hemp Oil. He also trained and worked as a neonatologist, and is on the clinical faculty at the University of Colorado School of Medicine.

10. Kristen Park, MD (*Neurologist*)
    Dr. Kristen Park is a pediatric neurologist at the Children's Hospital Colorado where she specializes in caring for children with epilepsy, the majority of whom have intractable seizures. She is also an Assistant Professor of Pediatrics at the University of Colorado School of Medicine.

11. Paula Riggs, MD (*Addiction medicine specialist*)
    Dr. Paula Riggs is a Professor of Psychiatry at the CU School of Medicine and Director of the Division of Substance Dependence. She is nationally known for her clinical research in adolescents with co-occurring psychiatric and substance abuse disorders.

12. Teri Robnett (*Patient representative*)
    Ms. Teri Robnett is founder and Executive Director of Cannabis Patients Alliance, a recently (2013) formed grassroots membership organization dedicated to medical marijuana political action and public education. She helped open the first large medical marijuana dispensary in central Denver in 2009 and served as Communications Director.

13. Alan Shackelford, MD (*Physician familiar with medical marijuana administration*)
    Dr. Alan Shackelford has accumulated a considerable amount of clinical experience on the medical uses of cannabis since 2009, and has evaluated patients with a variety of different serious medical conditions for whom cannabis proved to be a viable treatment option. He has also advised several state and foreign governments on medical cannabis legislation and regulatory structures, and has served on several state and local governmental advisory boards in Colorado dealing with cannabis regulation.

Attachment C: Caregiver Data
Data for Patients with an Active Card as of 3/31/14
Data Generated 6-27-14
Correction of 4-2-14

Caregiver Patient Load		
Number of Patients	Number of caregivers w/ specific patient count	% of caregivers w/specific count
1 Count	**2224**	75.36%
2 Count	**380**	12.88%
3 Count	**194**	6.57%
4 Count	**99**	3.35%
5 Count	**36**	1.22%
6 Count	**9**	0.30%
7 Count	**4**	0.14%
8 Count	**2**	0.07%
12 Count	**1**	0.03%
20 Count	**1**	0.03%
70 Count	**1**	0.03%
Total number of caregivers	2951	
Total number of caregivers with more than five patients	18	<0.01%

Attachment D: Distance Comparison from Patient's Residence to Caregiver versus Medical Marijuana Center
Data extracted June 1, 2014

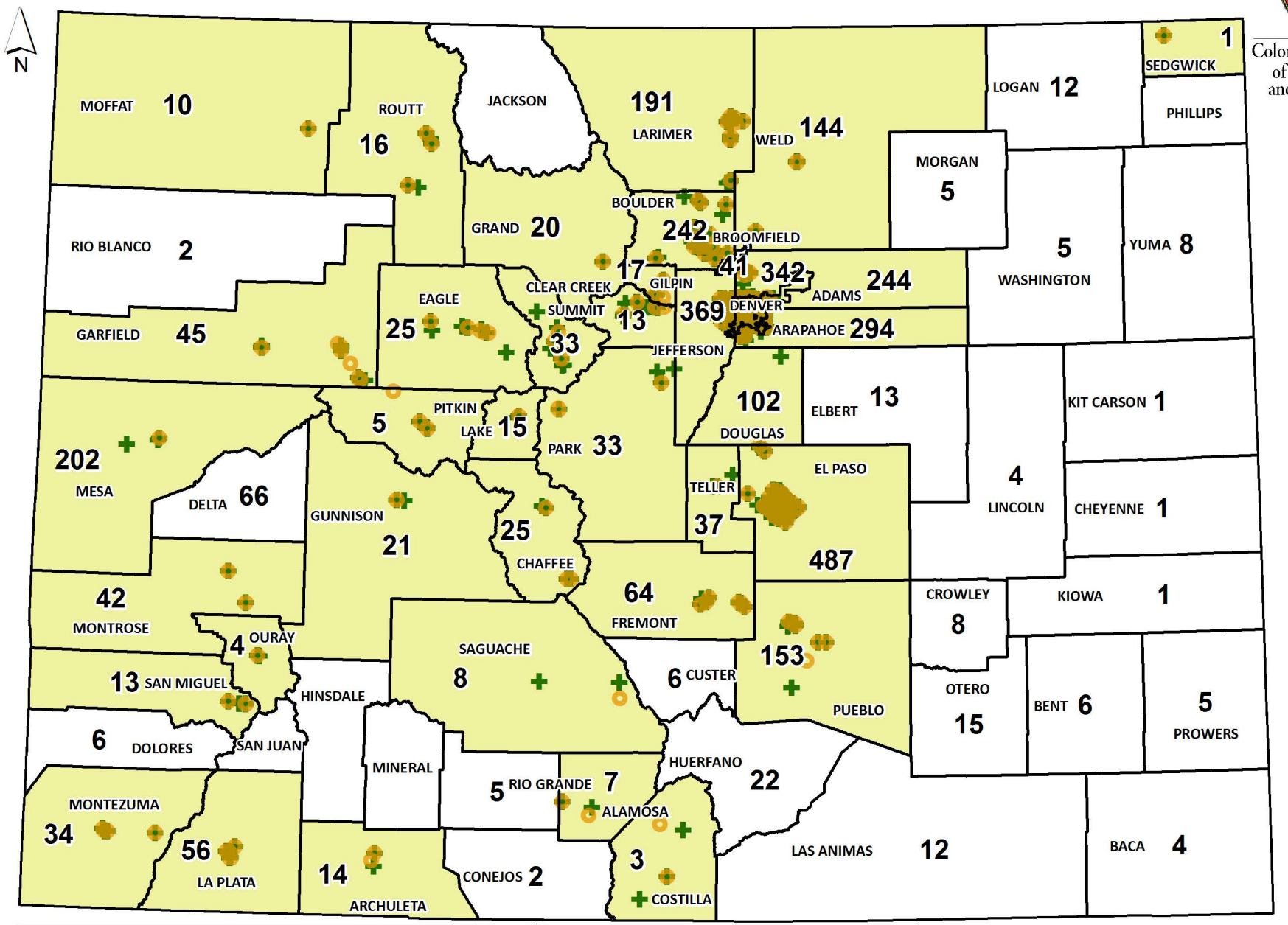
COUNTY	Average Distance to Caregiver	Average Distance to MMC		COUNTY	Average Distance to Caregiver	Average Distance to MMC
Adams	12.49	0.17		Kit Carson	85.12	6.3
Alamosa	12.4	0.17		La Plata	28.72	6.45
Arapahoe	11.76	0.29		Lake	4.9	6.65
Archuleta	11.66	0.29		Larimer	11.14	7.49
Baca	11.57	0.3		Las Animas	0.09	8.58
Bent	45.46	0.53		Lincoln	16.15	8.69
Boulder	11.91	0.65		Logan	5.55	8.75
Broomfield	11.65	0.79		Mesa	14.72	10.9
Chaffee	10.29	0.82		Moffat	14.01	13.16
Cheyenne	*	*		Montezuma	13.95	13.43
Clear Creek	17.01	0.84		Montrose	13.21	14.06
Conejos	199.86	4.21		Morgan	21.16	14.41
Costilla	74.28	5.07		Otero	34.88	14.56
Crowley	20.01	0.85		Ouray	74.87	14.64
Custer	46.84	0.86		Park	9.73	15.06
Delta	10.58	0.9		Phillips	46.35	15.55
Denver	14.03	1.25		Pitkin	16.33	15.78
Dolores	0	1.64		Prowers	3.3	15.93
Douglas	10.33	1.79		Pueblo	11.51	19.04
Eagle	31.02	1.96		Rio Blanco	*	*
El paso	9.6	2.83		Rio Grande	42.03	22.97
Elbert	7.91	3.81		Routt	13.42	24.37
Fremont	11.61	3.91		Saguache	67.56	26.06
Garfield	27.38	4.07		San Miguel	48.09	26.77
Gilpin	16.76	4.18		Sedgwick	*	*
Grand	18.7	4.26		Summit	17.65	27.97
Gunnison	19.29	4.37		Teller	15.09	31.05
Huerfano	34.8	4.47		Washington	10.5	33.97
Jackson				Weld	13.96	52.91
Jefferson	13.78	5.36		Yuma	17.57	119.4
Kiowa	*	*				

*Represent counties in which three or fewer patients reside. Data suppressed to protect confidentiality.

Counties where the average distance to caregiver is more than 20 miles from patient's residence, and a medical marijuana center is significantly closer.

Number of Caregivers Registered with Medical Marijuana Registry by County, State of Colorado, April 2014

Colorado Department of Public Health and Environment



Licensed Medical Marijuana Centers (DOR)

Medical Marijuana Centers

Counties With MMC's

The number in each county represents the number of caregivers registered with the Medical Marijuana Registry

0 12.5 25 50 75 100 Miles

STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
5CCR 1006-2 MEDICAL USE OF MARIJUANA
July 16, 2014

Basis and Purpose.
The proposed amendment consists of adding a new regulation to the existing rules regarding the administration of the new Colorado Medical Marijuana Research Grant Program created by SB 14-155. In addition, the proposed rules include updates to utilize current terms, align with Department of Revenue regulations where appropriate, and clarify Medical Marijuana Registry (MMR) processes.

Specific Statutory Authority.
Colorado Constitution, Article XVIII, Section 14
§ 25-1.5-106, C.R.S. and § 25-1.5-106.5, C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

__X___ Yes, the bill number is _SB 14-155_; rules are __ authorized _X_ required.
_____ No

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

_____ Yes
__X___ No

Does this rule incorporate materials by reference?

_____ Yes
__X __ No

Does this rule create or modify fines or fees?

_____ Yes
___X__ No

REGULATORY ANALYSIS
for Amendments to
5CCR 1006-2 MEDICAL USE OF MARIJUANA
July 16, 2014

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.**

   Stakeholders include current and future users of medical marijuana, caregivers, medical marijuana centers, law enforcement officers, and the Department of Revenue. The addition of the Research Grant Program will also impact any nonprofit or for-profit, private, public, or governmental organization with adequately trained researchers to conduct this research. Researchers who are awarded grants under this new program will benefit from the proposed rule. Current and future users of medical marijuana, along with caregivers and medical marijuana centers will benefit from an improved understanding of the therapeutic uses of marijuana and a potential expansion of the list of approved debilitating conditions for use of medical marijuana.

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.**

   RESEARCH: Researchers who are awarded grants under this new program will benefit from the proposed rule by the receipt of funds to support their research. Current and future users of medical marijuana, along with caregivers and medical marijuana centers will benefit from an improved understanding of the therapeutic uses of marijuana and a potential expansion of the list of approved debilitating conditions for use of medical marijuana.

   MEDICAL MARIJUANA CENTER REPORTING BY PATIENTS**:** Adjusting medical marijuana center reporting requirements to align with Department of Revenue regulations reduces patients' time, effort and eliminates a financial investment in providing documentation to the MMR. Eliminating this requirement also creates an efficiency for MMR staff which translates to improve card issuance and replacement timelines.

   CAREGIVERS: Caregivers benefit by having clear parameters set on the total number of patients in which they can provide care-giving services to, ensuring that they provide more than just marijuana to the patient. The community in general benefits from the decreased risk created by large, unregulated grow sites. These measures improve the department's ability to be responsive to the State Auditor's findings regarding the need for more effective mechanisms to oversee caregivers.

   PROOF OF RESIDENCY: Patients with non-Colorado identification may have increased time and financial investment to secure a Colorado-issued identification; however, the waiver process is available to support applicants and ensure that acquiring the residency documentation is not an undue burden. Applicants may experience a more expedited approval process, as proof of residency is one of the most common reasons for application rejection. Altered proof of residency is the number one reason for denied applications. Approximately 20 percent of applications come with non-Colorado identification and proof of residency paperwork.

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.**

   The proposed amendments do not result in additional costs to the Department. The statute authorizing the proposed rule regarding the Research Grant Program and the Scientific Advisory Committee authorizes use of existing medical marijuana program cash funds for the Department to both administer the grant program and fund the research grants. All other changes are

administrative in nature, and as described below, should result in reduced costs associated with the processing of applications and change forms.

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

   RESEARCH: Inaction deprives Colorado of the opportunity to study the therapeutic benefits of medical marijuana and would place the Department out of compliance with the statutory mandate to promulgate rules to implement the Research Grant Program.

   MEDICAL MARIJUANA CENTER REPORTING BY PATIENTS: Eliminating this requirement creates efficiency for patients, the MMR and eliminates a duplication of effort across state agencies.

   CAREGIVERS: Caregiver limitations directly impact patient quality of service and community risks associated with large, unregulated grow sites. The State Auditor found "Public Health has not established a process for caregivers to indicate the significant responsibilities they are assuming for managing the well-being of their patients or for documenting exceptional circumstances that require a caregiver to take on more than five patients." The proposed changes strengthen the Department's caregiver oversight while aligning with current caregiver practice. Inaction could indicate non-responsiveness to this finding.

   PROOF OF RESIDENCY: The Department could continue the current practice; however, placing the requirement in rule increases transparency. Simplifying the residency documentation requirement assists applicant's with applying, MMR staff with verifying documentation, and will impact the rejection rate. Residency documentation is a primary reason for rejection and denial of applications, and creates delays for applicants. Applicants with rejected proof of residency documentation could wait up to 90 days before receiving a registration card. Requiring Colorado-issued IDs with minimal exception will reduce the rejection rate and shorten the approval time for these patients. The waiver process is available to support applicants and ensure that acquiring the residency documentation is not an undue burden.

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

   There is not a less costly method. The rules enact the requirements of a new statute, align and streamline registry administrative practices.

6. **A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.**

   Rulemaking is required to comply with SB14-155. The remainder of changes improve the existing rules by improving efficiency, eliminating unnecessary requirements and responding to audit findings while aligning with the caregiver community practices.

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 researched other states' medical marijuana programs, state regulations, and MMR patient and caregiver data, and consulted with the Office of the Attorney General. The short-term and long-term consequences are improved application and patient record processing and an improved understanding of medical marijuana. The waiver process and establishing a caregiver maximum patient count strengthens Department oversight to ensure patients are supported.

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

The following individuals and/or entities were included in the development of these proposed rules:

- The Department held a Town Hall meeting on April 25, 2014 at which more than 100 patients, caregivers, physicians and other community advocates provided input regarding caregiver limits and purposes.
- A stakeholder's survey is currently available through our website for stakeholder input on the proposed rule. Notice of the survey was posted through the CDPHE Facebook and Twitter feeds, and an electronic newsletter to all stakeholders who have signed up for notices.
- The Department consulted with other state agencies including the Department of Revenue and the Attorney General's Office. The Department met with the Department of Revenue Marijuana Enforcement Division's leadership to identify ways to increase oversight of medical marijuana centers and reduce duplication of efforts. The rule-making recommendation is part of the process recommended.
- An electronic notice was sent to all 580 contacts who have subscribed for electronic notices through our website. In addition, a Facebook and Twitter notice was sent through the CDPHE pages to announce the upcoming request for a rule-making hearing and to provide the link to the stakeholder's survey.
- This request for rulemaking packet is available on the Department's website and comments can be submitted to the MMR.

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

In addition to the individuals and entities identified above, law enforcement personnel have also been notified of the upcoming request for rulemaking.

On or before the date of publication of the notice in the Colorado Register, the Division sent notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/ information from the division regarding the proposed rule-making? __Yes ____ No. The Division provided notice on ____NA____.

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 Department is in the course of gathering additional stakeholder feedback. The Department of Revenue is in favor of changes to caregiver and medical marijuana center recommendations.

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?

The recommendations impact Coloradoans equally and equitably.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health and Environmental Information and Statistics Division

MEDICAL USE OF MARIJUANA

5 CCR 1006-2

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

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

A. The Colorado Department of Public Health and Environment ("the department") shall create and maintain a confidential registry ("the registry") of patients who have applied for and are entitled to receive a registry identification card.

1. All personal medical records and personal identifying information held by the department in compliance with these regulations shall be confidential information.

2. No person shall be permitted to gain access to any information about patients in this registry, or any information otherwise maintained in the registry by the department about physicians and primary care-givers of patients in the registry, except for authorized employees of the department in the course of their official duties and authorized employees of state and local law enforcement agencies which have stopped or arrested a person who claims to be engaged in the medical use of marijuana and in possession of a registry identification card issued pursuant to regulations two and three, or the functional equivalent of the registry identification card.

a. Department employees may, upon receipt of an inquiry from a state or local law enforcement agency, confirm that a registry identification card has been suspended when a patient is no longer diagnosed as having a debilitating medical condition.

b. Authorized department employees may respond to an inquiry from state or local law enforcement regarding the registry status of a patient or primary care-giver by confirming that the person is or is not registered. The information released to state and local law enforcement must be the minimum necessary to confirm registry status.

c. Authorized state and local law enforcement employees shall validate their inquiry of a patient or primary care-giver by producing the registry identification card number of a patient, or name, date of birth, and last four digits of the individual's social security number of the individual under inquiry if the person does not have a registry identification card.

d. Authorized department employees may confirm a waiver for homebound or minor patients' transportation of medical marijuana from a medical marijuana center or a waiver for a primary care-giver serving more than five patients, upon state or local law enforcement inquiry. The minimum necessary information shall be communicated to confirm or deny a waiver.

3. The department may release information concerning a specific patient to that patient with the written authorization of such patient.

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

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

C. DEFINITIONS

1. AN "ADULT APPLICANT" IS DEFINED AS A PATIENT EIGHTEEN YEARS OF AGE OR OLDER.

2. A "MINOR APPLICANT" IS DEFINED AS A PATIENT LESS THAN EIGHTEEN YEARS OF AGE.

3. “COUNCIL” MEANS THE MEDICAL MARIJUANA SCIENTIFIC ADVISORY COUNCIL APPOINTED BY THE EXECUTIVE DIRECTOR OF THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT PER REQUIREMENTS ESTABLISHED IN SECTION 25-1.5-106.5, C.R.S.

4. “GRANT PROGRAM” MEANS THE COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM CREATED IN SECTION 25-1.5-106.5, C.R.S. TO FUND RESEARCH INTENDED TO ASCERTAIN THE EFFICACY OF ADMINISTERING MARIJUANA AND ITS COMPONENT PARTS AS PART OF MEDICAL TREATMENT.

5. "PRIMARY CARE-GIVER" OR “PRIMARY CAREGIVER” MEANS A PERSON OTHER THAN THE PATIENT AND THE PATIENT’S PHYSICIAN, WHO IS EIGHTEEN YEARS OF AGE OR OLDER AND HAS SIGNIFICANT RESPONSIBILITY FOR MANAGING THE WELL-BEING OF A PATIENT WHO HAS A DEBILITATING MEDICAL CONDITION

6. "SIGNIFICANT RESPONSIBILITY FOR MANAGING THE WELL-BEING OF A PATIENT" MEANS, IN ADDITION TO THE ABILITY TO PROVIDE MEDICAL MARIJUANA, REGULARLY ASSISTING A PATIENT WITH ACTIVITIES OF DAILY LIVING, INCLUDING BUT NOT LIMITED TO TRANSPORTATION OR HOUSEKEEPING OR MEAL PREPARATION OR SHOPPING OR MAKING ANY NECESSARY ARRANGEMENT FOR ACCESS TO MEDICAL CARE OR OTHER SERVICES UNRELATED TO MEDICAL MARIJUANA. THE ACT OF SUPPLYING MEDICAL MARIJUANA OR MARIJUANA PARAPHERNALIA, BY ITSELF, IS INSUFFICIENT TO CONSTITUTE "SIGNIFICANT RESPONSIBILITY FOR MANAGING THE WELL-BEING OF A PATIENT."

Regulation 2: Application for a registry identification card

~~A. DEFINITIONS~~

~~i) An "adult applicant" is defined as a patient eighteen years of age or older. A "minor applicant" is defined as a patient less than eighteen years of age.~~

~~ii) "Primary care-giver" means a person other than the patient and the patient's physician, who is eighteen years of age or older and has significant responsibility for managing the well-being of a patient who has a debilitating medical condition. A person shall be listed as a primary care-giver for no more than five patients in the medical marijuana program registry at any given time unless a waiver has been granted for exceptional circumstances, as per Regulation Ten below.~~

~~iii) "Significant responsibility for managing the well-being of a patient" means, in addition to the ability to provide medical marijuana, regularly assisting a patient with activities of daily living, including but not limited to transportation or housekeeping or meal preparation or shopping or making any necessary arrangement for access to medical care or other services unrelated to medical marijuana. The act of supplying medical marijuana or marijuana paraphernalia, by itself, is insufficient to constitute "significant responsibility for managing the well-being of a patient."~~

A~~B~~. 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 form supplied by the department, and have such application notarized and 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. ~~The name and address of the applicant's primary care-giver or medical marijuana center, applicant's if either one is designated at the time of application. Only a~~ AT THE TIME OF APPLICATION, THE PATIENT WILL INDICATE WHETHER A PATIENT WILL UTILIZE A PRIMARY CARE-GIVER OR A MEDICAL MARIJUANA CENTER. ~~Only a~~ Homebound or minor patientS ~~may~~ must have ~~both~~ a primary care-giver ON RECORD. IF THE PRIMARY CARE-GIVER IS NOT GROWING MEDICAL MARIJUANA FOR THE PATIENT, THE PATIENT MAY ASSIGN PLANT GROW RIGHTS TO ~~and~~ a medical marijuana center.

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 MUST PROVIDE THE CENTER'S NAME AND DEPARTMENT OF REVENUE LICENSE NUMBER. THE MEDICAL MARIJUANA CENTER WILL REPORT CHANGES OF PATIENT COUNT TO THE DEPARTMENT OF REVENUE PER REGULATIONS. MEDICAL MARIJUANA CENTER INFORMATION IS NOT REFLECTED ON THE REGISTRATION CARD.

3. Written documentation from the applicant's physician that the applicant has been diagnosed with a debilitating medical condition as defined in regulation six and the physician's conclusion that the applicant might benefit from the medical use of marijuana;

4. A statement from the physician if the patient is homebound, if applicable;

5. The name, address, and telephone number of the physician who has concluded the applicant might benefit from the medical use of marijuana; and

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

7. PROOF OF RESIDENCY MUST BE ESTABLISHED AT TIME OF APPLICATION. PROOF OF RESIDENCY MUST CONTAIN A PHOTOGRAPH AND DATE OF BIRTH, THE FOLLOWING CAN BE USED TO ESTABLISH COLORADO RESIDENCY:

A. VALID STATE OF COLORADO DRIVER'S LICENSE;

B. VALID STATE OF COLORADO IDENTIFICATION CARD; OR

C. ANY OTHER VALID GOVERNMENT-ISSUED PICTURE IDENTIFICATION THAT DEMONSTRATES THAT THE HOLDER OF THE IDENTIFICATION IS A COLORADO RESIDENT.

D. NO COMBINATION OF IDENTIFICATION OR DOCUMENTS MAY BE USED TO ESTABLISH RESIDENCY.

8. APPLICANTS WHO ARE UNABLE TO PROVIDE THE ABOVE-REQUIRED PROOF OF IDENTIFICATION AND/OR RESIDENCY PAPERWORK MAY SUBMIT A REQUEST FOR A DOCUMENTATION WAIVER.

B ~~C~~. 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 form supplied by the department, and have such application notarized, 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. Written documentation from two of the applicant's physicians that the applicant has been diagnosed with a debilitating medical condition as defined in regulation six and each physician's conclusion that the applicant might benefit from the medical use of marijuana;

3. The name, address, and telephone number of the two physicians who have concluded the applicant might benefit from the medical use of marijuana;

4. Consent from each of the applicant's parents residing in Colorado that the applicant may engage in the medical use of marijuana;

5. Documentation that one of the physicians referred to in (iii) has explained the possible risks and benefits of medical use of marijuana to the applicant and each of the applicant's parents residing in Colorado; and

6. The name and ~~address~~ DEPARTMENT OF REVENUE LICENSE NUMBER of the applicant's medical marijuana center, if one is designated at the time of application.

C ~~D~~. To maintain an effective registry identification card, a patient must annually resubmit to the department, at least thirty days prior to the expiration date, but no sooner than sixty days prior to the expiration date, updated written documentation of the information required in paragraphs B and C of this regulation. In addition, the patient must provide the name and address of the primary care-giver, or the name and ~~address~~ DEPARTMENT OF REVENUE LICENSE NUMBER of a medical marijuana center, if either is designated at such time.

D. ~~E.~~ A patient may change his or her primary care-giver WITH THE DEPARTMENT ~~or medical marijuana center~~ no more than once per month. CHANGES IN DESIGNATED PRIMARY MEDICAL MARIJUANA CENTER ARE REPORTED BY THE MEDICAL MARIJUANA CENTER TO THE MARIJUANA ENFORCEMENT DIVISION PER DEPARTMENT OF REVENUE REGULATIONS. A patient may change his or her primary care-giver ~~or medical marijuana center~~ by submitting such information on the form and in the manner as directed by the department within ten days of the change occurring.

E. ~~F.~~ Rejected applications. Rejected applications shall not be considered pending applications, and shall not be subject to the requirement in the Constitution that applications be deemed approved after thirty-five days. The department may reject as incomplete any patient application for any of the following reasons:

1. If information contained in the application is illegible or missing;

2. If the application is not notarized; or

3. The physician(s) is/are not eligible to recommend the use of marijuana.

4. An applicant shall have (60) days from the date the department mails the rejected application to make corrections and resubmit the application.

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

1. The physician recommendation is falsified;

2. Any information on the application is falsified;

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

4. The applicant is not a Colorado resident;

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

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

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

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

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

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

I. ~~J.~~ Appeals. If the department denies an application or, suspends or, revokes a registry identification card, the department shall provide the applicant/patient with notice of the grounds for the denial, suspension, or revocation, and shall inform the patient of the patient's right to request a hearing. ~~1.~~ A request for hearing shall be submitted to the department in writing within thirty (30) calendar days from the date of the postmark on the notice.

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

2.~~b.~~ If a request for a hearing is made, the hearing shall be conducted in accordance with the state Administrative Procedures Act, § 24-4-101, et seq., C.R.S.

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

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

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

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

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

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

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

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

a. If there are no peer-reviewed published studies of randomized controlled studies OR WELL-DESIGNED OBSERVATIONAL STUDIES showing efficacy in humans for use of medical marijuana for the condition that is the subject of the petition;

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

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

3. ~~Ad hoc~~ Medical MARIJUANA SCIENTIFIC advisory ~~panel~~ COUNCIL.

a. THE MEDICAL MARIJUANA SCIENTIFIC ADVISORY COUNCIL SHALL PERFORM ALL OF THE FOLLOWING DUTIES:

i. OBJECTIVELY EVALUATE RESEARCH PROPOSALS AND PROVIDE A PEER REVIEW PROCESS THAT GUARDS AGAINST FUNDING RESEARCH THAT IS BIASED IN FAVOR OR AGAINST PARTICULAR OUTCOMES FOR PROPOSALS SUBMITTED FOR THE COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM;

ii. PROVIDE POLICY GUIDANCE IN THE CREATION AND IMPLEMENTATION OF THE COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM AND IN SCIENTIFIC OVERSIGHT AND REVIEW, AND;

iii. REVIEW PETITIONS TO ADD A DEBILITATING MEDICAL CONDITION TO THE REGISTRY AND MAKE A DENIAL OR APPROVAL RECOMMENDATION TO THE DEPARTMENT.

b. The ~~department shall establish an ad hoc A~~ medical MARIJUANA SCIENTIFIC advisory ~~panel~~ COUNCIL ~~to~~ will review petitions TO ADD DEBILITATING MEDICAL CONDITIONS if the conditions for denial set forth in paragraphs (2)(a),(b) and (c) of this section D are not met.

~~b. Composition of the ad hoc medical advisory panel shall be as follows:~~

~~i. One physician in the appropriate field for the condition requested to be added who is recommended by the petitioner who meets appropriate qualifications with no objective evidence of bias;~~

~~ii. One physician in the appropriate field for the condition requested to be added who is recommended by the department who meets appropriate qualifications with no objective evidence of bias;~~

~~iii. One physician who recommends medical marijuana in his or her practice, who may be recommended by the petitioner;~~

~~iv. One physician in addiction medicine; and~~

~~v. The executive director or his or her designee, or, if the executive director is not a physician, the state chief medical officer.~~

c~~.~~ The ~~ad hoc medical advisory panel~~ COUNCIL shall review the petition information presented to the department and any further medical research related to the condition requested, and make recommendations to the executive director, or his or her designee, regarding the petition.

~~d. If the department is unable to recruit participants for the ad hoc medical advisory panel, the department shall seek informal consultation from individuals meeting the criteria listed in this paragraph (2)(a).~~

d. ~~e. Department requests for rulemaking hearings on petitions to add debilitating medical conditions.~~ Within (120) days of receipt of a petition to add a debilitating medical condition, the department shall petition the board for a rulemaking hearing to consider

adding the condition to the list of debilitating medical conditions if the COUNCIL ~~ad hoc medical advisory panel~~ recommends approval of the petition to add the condition.

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

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

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

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

A. In exceptional circumstances, a waiver may be granted by the department for the purpose of allowing a primary care-giver to serve more than five patients. A separate waiver application will be required by each patient seeking to use a primary care-giver who is already at the five patient limit. If the department does not act upon the waiver application within 35 days, the waiver shall be deemed approved until acted upon by the department. WHERE WAIVERS APPLY, CARE-GIVERS WILL BE ALLOWED TO SERVE A MAXIMUM OF 10 PATIENTS AT A TIME.

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

C. The patient and primary care-giver shall provide the department such information and documentation as the department may require validating the conditions under which the waiver is being sought.

D. In acting on the waiver application, the department shall consider at a minimum all of the following:

1. The information submitted by the patient applicant;

2. The information submitted by the primary care-giver;

3. COUNTY-WIDE PROHIBITIONS ON MEDICAL MARIJUANA CENTERS;

4. ~~3.~~ The proximity of medical marijuana centers to the patient;

5. ~~4.~~ Whether granting the waiver would either benefit or adversely affect the health, safety or welfare of the patient; and

6. ~~5.~~ What services beyond providing medical marijuana the patient applicant needs from the proposed primary care-giver.

E. The department may specify terms and conditions under which any waiver is granted, and which terms and conditions must be met in order for the waiver to remain in effect.

F. The term for the waiver shall be one year unless the care-giver reduces the number of patients he or she serves during that year to five or fewer, at which time the waiver shall expire. The care-giver shall notify the department in writing when he or she no longer provides care-giver services to a patient.

G. At any time, upon reasonable cause, the department may review any existing waiver to ensure that the terms and conditions of the waiver are being observed and or that the continued existence of the waiver is appropriate.

H. The department may revoke a waiver if it determines that any one of the following is met:

1. The waiver jeopardizes the health, safety and welfare of patients;

2. The patient applicant or care-giver has provided false or misleading information in the application;

3. The patient applicant or care-giver has failed to comply with the terms or conditions of the waiver;

4. The conditions under which a waiver was granted no longer exist or have materially changed; or

5. A change in state law or regulation prohibits or is inconsistent with the continuation of the waiver.

I. The department will provide notice of the revocation of the waiver to the registered patient and the care-giver at the time the waiver is revoked.

J. Appeals. If the department proposes to deny, condition, revoke or suspend a waiver for a primary care-giver to serve more than five patients, the department shall provide the patient with notice of the grounds for the action and shall inform the patient of the patient's right to request a hearing.

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

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

3. If a request for a hearing is made, the hearing shall be conducted in accordance with the state Administrative Procedures Act, § 24-4-101 et seq., C.R.S.

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

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Regulation 12: Patient Responsibilities.

A. ~~Patient shall make a copy of his/her application along with proof of the date of submission available to his/her designated primary care-giver when it has been more than thirty-five days since the date the patient filed his or her medical marijuana application and the department has neither issued a registry identification card nor denied the application.~~ A PATIENT SHALL PROVIDE HIS/HER CAREGIVER WITH A COPY OF HIS/HER APPLICATION, PHYSICIAN CERTIFICATION AND REGISTRATION CARD, ONCE ISSUED. A copy of the patient's application AND REGISTRATION CARD shall be in the primary care-giver's possession at all times that the primary care-giver is in possession of marijuana. The patient may obscure or redact the mailing address and social security number on the copy of the application OR REGISTRATION CARD given to the primary care-giver.

B. When a patient changes his or her primary care-giver ~~or medical marijuana center~~, the patient shall submit notice of the change on the form and in the manner as directed by the department. THE PATIENT SHALL GIVE A COPY OF THE SUBMITTED FORM TO THE PRIMARY CARE-GIVER. THE PATIENT MAY OBSCURE OR REDACT THE MAILING ADDRESS AND SOCIAL SECURITY NUMBER ON THE COPY OF THE FORM GIVEN TO THE PRIMARY CARE-GIVER.

C. A patient shall not:

1. Engage in the medical use of marijuana in a way that endangers the health and well-being of a person;

2. Engage in the medical use of marijuana in plain view of or in a place open to the general public;

3. Undertake any task while under the influence of medical marijuana, when doing so would constitute negligence or professional malpractice;

4. 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;

5. Engage in the use of medical marijuana while:

a. In a correctional facility or a community corrections facility;

b. Subject to a sentence to incarceration;

c. In a vehicle, aircraft, or motorboat; or

d. As otherwise ordered by the court.

6. Operate, navigate, or be in actual physical control of any vehicle, aircraft, or motorboat while under the influence of medical marijuana; or

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

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

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

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

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

F. A patient shall not establish a business to permit other patients to congregate and smoke or otherwise consume medical marijuana.

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REGULATION 14: COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM

A. PROCEDURES FOR GRANT APPLICATION TO THE GRANT PROGRAM

1. GRANT APPLICATION CONTENTS.

a. AT A MINIMUM, ALL APPLICATIONS SHALL BE SUBMITTED TO THE DEPARTMENT IN ACCORDANCE WITH THESE RULES AND SHALL CONTAIN THE FOLLOWING INFORMATION:

i. A DESCRIPTION OF KEY PERSONNEL, INCLUDING CLINICIANS, SCIENTISTS, OR EPIDEMIOLOGISTS AND SUPPORT PERSONNEL, DEMONSTRATING THEY ARE ADEQUATELY TRAINED TO CONDUCT THIS RESEARCH.

ii. PROCEDURES FOR OUTREACH TO PATIENTS WITH VARIOUS MEDICAL CONDITIONS WHO MAY BE SUITABLE PARTICIPANTS IN RESEARCH ON MARIJUANA.

iii. PROTOCOLS SUITABLE FOR RESEARCH ON MARIJUANA AS MEDICAL TREATMENT INCLUDING PROCEDURES FOR COLLECTING AND ANALYZING DATA AND STATISTICAL METHODS TO BE USED TO ASSESS SIGNIFICANT OUTCOMES.

iv. DEMONSTRATION THAT APPROPRIATE PROTOCOLS FOR ADEQUATE PATIENT CONSENT AND FOLLOW-UP PROCEDURES ARE IN PLACE.

v. A PROCESS FOR A GRANT RESEARCH PROPOSAL APPROVED BY THE GRANT PROGRAM TO BE REVIEWED AND APPROVED BY AN INSTITUTIONAL REVIEW BOARD THAT IS ABLE TO APPROVE, MONITOR, AND REVIEW BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS.

2. TIMELINES FOR GRANT APPLICATION.

GRANT APPLICATIONS MAY BE SOLICITED ON DATES DETERMINED BY THE DEPARTMENT.

B. CRITERIA FOR SELECTING ENTITIES

1. THE FOLLOWING CRITERIA SHALL BE USED FOR SELECTING POTENTIAL GRANTEES:

a. THE APPLICANT SUBMITS A COMPLETED APPLICATION IN ACCORDANCE WITH THE REQUIREMENTS IN SECTION A.1.;

b. THE SCIENTIFIC MERIT OF THE RESEARCH PLAN, INCLUDING WHETHER THE RESEARCH DESIGN AND EXPERIMENTAL PROCEDURES ARE POTENTIALLY BIASED FOR OR AGAINST A PARTICULAR OUTCOME.

c. THE RESEARCHERS' EXPERTISE IN THE SCIENTIFIC SUBSTANCE AND METHODS OF THE PROPOSED RESEARCH AND THEIR LACK OF BIAS OR CONFLICT OF INTEREST REGARDING THE TOPIC OF, AND THE APPROACH TAKEN IN, THE PROPOSED RESEARCH.

d. THE APPLICANT HAS THE CAPACITY TO ADEQUATELY ADMINISTER AND IMPLEMENT THE GRANT INCLUDING THE CAPACITY TO MEET ITS RESPONSIBILITIES DELINEATED IN SECTION C.

2. THE COUNCIL SHALL SUBMIT RECOMMENDATIONS FOR GRANTS TO THE STATE BOARD OF HEALTH, WHICH SHALL APPROVE OR DISAPPROVE OF GRANTS SUBMITTED BY THE COUNCIL. IF THE STATE BOARD OF HEALTH DISAPPROVES A RECOMMENDATION, THE COUNCIL MAY SUBMIT A REPLACEMENT RECOMMENDATION WITHIN THIRTY DAYS.

3. THE STATE BOARD OF HEALTH SHALL AWARD GRANTS TO THE SELECTED ENTITIES, SPECIFYING THE AMOUNT AND DURATION OF THE AWARD, WHICH CANNOT EXCEED THREE YEARS WITHOUT RENEWAL.

C. GRANTEE REPORTING

1. PROGRESS REPORTS. GRANTEES SHALL BE RESPONSIBLE FOR ONGOING REPORTING CONSISTING OF THE FOLLOWING:

a. QUARTERLY PROGRESS REPORTS

b. ANNUAL UPDATES WHICH MAY REPLACE THE FOURTH FISCAL QUARTER REPORT

c. FINAL REPORT AT THE END OF THE GRANT CYCLE.

2. AT A MINIMUM, ALL PROGRESS REPORTS, ANNUAL UPDATES AND FINAL REPORTS SHALL INCLUDE THE NUMBERS OF PATIENTS ENROLLED IN EACH STUDY AND ANY SCIENTIFICALLY VALID PRELIMINARY FINDINGS.

3. ALL PROGRESS REPORTS, ANNUAL UPDATES AND FINAL REPORT SHALL BE SUBMITTED TO THE COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM. REPORTS SHALL BE SUBMITTED ELECTRONICALLY IN ANY WORD PROCESSING SOFTWARE PROGRAM COMPATIBLE WITH MICROSOFT WORD 2007 OR HIGHER FORMAT.

4. GRANTEES WHO FAIL TO SUBMIT ANY OF THE REQUIRED REPORTS MAY BE TERMINATED FROM THE GRANT PROGRAM FOR NON-PERFORMANCE. IN THE EVENT THAT GRANTEES FAIL TO SUBMIT A FINAL REPORT AFTER THE CONCLUSION OF THEIR GRANT, FUTURE APPLICATIONS OF THE GRANTEE MAY BE DENIED BASED ON PRIOR NON-PERFORMANCE.