



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

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: **September 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. **Community input and comment was received via a stakeholder survey available June 15 to July 31, 2014. 129 individuals responded to the survey. Survey results and summarized comments are attached, Attachment B.**

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. The current council member in the ad hoc position may be replaced, for the purpose of petition review, by a physician in the appropriate field for the condition requested or recommended by the petitioner. A comparison of the committee requirements and a brief biography of the appointed council members is attached to this memo, Attachment C.

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 majority of respondents (74%) to the above-mentioned stakeholder survey agreed the Registry should require Colorado-issued identification as proof of residency. A summary of comments from those who do not agree and the Department's response is attached, Attachment B.

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. The majority (80%) of survey respondents agree the Registry should no longer require applicants to list the medical marijuana data on the application and no longer report changes in their assigned medical marijuana centers. A summary of comments from those who do not agree and the Department response is attached, Attachment B.

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 31, 2014, there were 2,896 individuals listed as caregivers representing a total of 4,371 active patients. Of these caregivers 2,876 (99.3%) served five or fewer patients. Of the less than 1% of caregivers who served more than five patients, 16 (80%) served 10 or fewer patients. Caregiver Data is attached to this memo, Attachment D. 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 E. 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.

The survey indicates that 41% support or have no concern with a maximum patient limit and 59% preferred no limit. A summary of comments from those who do not agree and the Department response is attached, Attachment B. The Department continues to recommend a maximum patient count for caregivers. For survey respondents concerned with the business impact, the Department would urge those caregivers to assess whether they should be operating as a dispensary rather than serving as a caregiver. Establishing a maximum limit addresses the findings of the State Auditor that concern the oversight of caregivers and assist with distinguishing caregivers from dispensaries. The proposed maximum was specifically sought because it aligns with over 99% of the current practice. The Department appreciates the impact to four of the 2,876 caregivers that exceed the proposed maximum of ten patients; however,

the department and the caregiver community as a whole benefits from the clarity that comes from establishing a caregiver maximum.

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 an 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: Stakeholder Survey Responses & Comments

Survey available from June 6 to July 31, 2014

Total Survey Participants: 129

Question #1: Proof of Residency

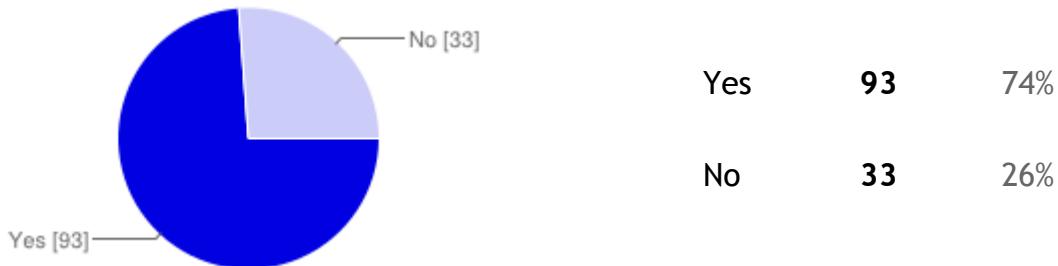
Colorado constitution requires residency as a criteria for Registry participation. The Registry is proposing that proof of residency regulations be adjusted to match residency requirements established by 1 CCR 212-2 the "Colorado Retail Marijuana Code." Regulations would be amended as follows:

As long as it contains a picture and date of birth, the kind and type of identification deemed adequate to establish Colorado residency shall be limited to the following:

1. Valid state of Colorado driver's license;
2. Valid state of Colorado identification card; or
3. Any other valid government-issued picture identification that demonstrates that the holder of the identification is a Colorado resident.
4. No combination of identification or documents may be used to establish residency.

Patients who are not able to provide one of the above forms of identification and proof of residency may submit a waiver request.

Do you agree that Colorado-issued identification should be required for proof of residency?

**Summary of the comments from those that selected No:**

- Two commented that the current process is working well.
- Seven commented that requiring a Colorado ID will create delays for individuals who recently moved to the state.
- Seven commented that requiring a Colorado-issued ID increases difficulty for patients and that a combination of documents should be allowed to establish residency.
- Four commented that some individuals maintain dual residency with homes in more than one state and choose to maintain their ID from other states.

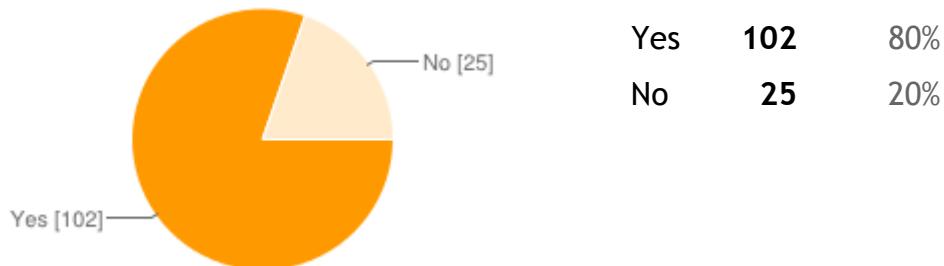
Department response:

- Proof of residency documentation is the number one reason for application rejection. Altered proof of residency documentation is the most frequent reason for application denials.
- Residency requirements are waived for active duty personnel and their dependents. Out-of-state students are exempt from obtaining a Colorado-issued ID.
- Applicants with dual residency may apply for a waiver.

Question #2: Reporting of Medical Marijuana Center Changes

To reduce the time and expense patients invest in submitting paperwork, we are requesting the Board of Health repeal regulations requiring patients to report medical marijuana center changes to the Registry.

Statute requires a patient to identify whether he/she will use a caregiver or medical marijuana center. Statute does not require applicants to report the name of the center to whom they have assigned growing rights. The proposed changes will no longer require an applicant to list the specific medical marijuana center on the application. MMR patients will also not be required to notify the Registry when he/she elects to change his/her medical marijuana center. Medical marijuana centers will continue to report patient counts in compliance with the Department of Revenue's regulations. Patients will still be required to provide medical marijuana centers with proof of registration.

**Summary of the comments from those that selected No:**

- Four commented that without reporting changes to medical marijuana centers, patients may designate their plant growth responsibilities to both a caregiver and a medical marijuana center.
- Thirteen commented that, if patients do not report changes in medical marijuana centers, the centers will not have an accurate record of patient and plant count assignments. There will be no way to provide regulatory oversight.
- One individual commented that, if a caregiver is not informed that a patient has switched to a medical marijuana center, he or she may be at risk of growing unauthorized plants.

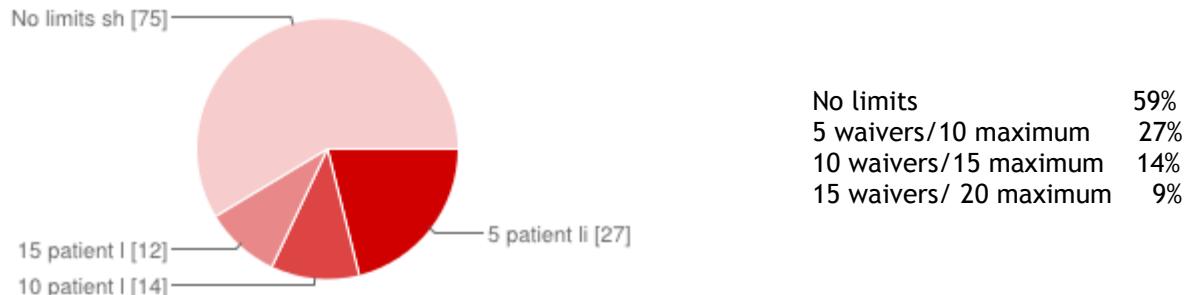
Department response:

- The Registry cannot notify caregivers of changes in patient records, including changes in plant growing designation. It is the patient's responsibility to inform the caregiver of changes.
- Patient assignment and plant counts are monitored through the Dept. of Revenue's Marijuana Inventory Tracking Solution (MITS). Due to constitutional confidentiality limits, the Registry does not provide patient information to DOR, thus listing the medical marijuana center in the database does not increase oversight.
- Per statute, medical marijuana centers cannot grow marijuana for patients who have assigned a caregiver, with the exception of homebound or patients under the age of 18. The registration card provides the name of the designated caregiver. Patients must submit a change of patient request to remove the designated caregiver before designating plant grow rights to a medical marijuana center.

Question #3: Patient Limit Waivers for Caregivers

Currently, more than 99% of caregivers on the Registry serve five or fewer patients. Of the remaining 1% of caregivers, 82% serve 10 or fewer patients. Only four caregivers serve more than 10 patients. We are proposing a limit on the number of patient limit waivers a caregiver can receive per year to ensure that caregivers can provide the best quality of care to patients per statutory requirements.

- 5 patient limit waivers per year, allowing caregivers to serve a maximum of 10 patients.
- 10 patient limit waivers per year, allowing caregivers to serve a maximum of 15 patients.
- 15 patient limit waivers per year, allowing caregivers to serve a maximum of 20 patients.
- No limits should be set on the number of patients a caregiver can serve.



Summary of the comments from those that selected No:

- Thirty-three commented that there is insufficient information to determine the number of patients a caregiver can effectively serve.
- Five commented that limiting the number of caregivers would prevent an enterprising caregiver from launching an operation adequate to service a number of patients. This limit would stifle potential business growth.
- Seven commented that some caregivers provide proprietary strains and potency of certain products that is not available through medical marijuana centers.
- Eighteen commented that many patients live in rural areas or in counties with bans on medical marijuana centers, limit waivers create barriers to access for these patients. Caregivers provide medical marijuana directly to patients.
- One commented that this was not what voters decided when they passed amendment 20.

Department response:

- 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. [Per C.R.S 25-1.5-106, caregivers shall have significant responsibility for managing the well-being of a patient with a debilitating condition AND the care-giving relationship must be more than providing medical marijuana or marijuana paraphernalia].
- Establishing a maximum limit clarifies the distinction between dispensaries and caregivers. Per C.R.S. 25-1.5-106(8)(d), “A primary caregiver may not charge a patient more than the cost of cultivating or purchasing the medical marijuana, but may charge for caregiver services.”
- Large caregiver grow sites become a public safety and environmental health concern with less structured oversight. A caregiver growing plants for 5 patients can legally grow 60+ plants. Caregivers can grow in residential areas. Because caregivers are not regulated businesses, there is nothing to assist caregivers or neighborhoods with ensuring the home is adequately equipped to grow 60+plants.
- The state audit of the Registry published in June 2013 found that the department needs to strengthen its oversight of caregiver activities by determining whether additional criteria are needed (e.g., number of people served, number of plants cultivated, and/or amount of finished marijuana product possessed) to identify a clear threshold that would differentiate caregivers from licensed businesses in Colorado. This, coupled with the Department completing a require of waiver applications pursuant to Regulation 10.D., ensures the Registry is accountable, comports the constitutional and statutory framework, and does so while aligning with the caregiver community’s practice.

**Attachment C: Comparison of Board of Health Regulation and Statutory Requirements
for the Advisory Council**

BOH Ad Hoc Committee	SB 14-155 Requirements	Scientific Advisory Council Members
Executive Director/CMO or designee	Chief Medical Officer or designee	Larry Wolk, MD, MSPH
One physician in the appropriate field for the condition requested – recommended by the petitioner		[PROPOSED] <i>Ad hoc</i> position (below) may be replaced, for the purpose of petition review, by a 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 <i>ad hoc</i> member with clinical expertise in the medical condition under study	Ken Finn, MD
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.	Lalit Bajaj, MD, MPH
	A medical toxicologist	Kennon Heard, MD
	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, MPH
	An alternative medicine specialist with expertise in herbal or alternative medicine	Stacy Livingwell, MD
	A person who represents medical marijuana patient interests	Teri Robnett

Scientific Advisory Council Members Biographies

Revised July 2014

1. Tim Byers, MD, MPH (Epidemiologist with expertise in large epidemiologic studies)

Dr. Tim Byers is a Professor of Epidemiology and Associate Dean for Public Health Practice at the Colorado School of Public Health. He has substantial expertise in large epidemiologic study design and analysis as a principal investigator or co-investigator on numerous grant funded research projects, author/co-author of numerous journal articles, grant reviewer for the National Institutes of Health, and manuscript reviewer for several high profile medical and public health journals. Dr. Byers brings substantial experience as a methodologist to the the council.

2. Lalit Bajaj, MD, MPH (Clinician with clinical trials expertise)

Dr. Lalit Bajaj is Director of the Children's Clinical Research Organization at Children's Hospital Colorado; and Associate Professor of Pediatrics and Emergency Medicine, as well as Research Director, Section of Emergency Medicine, at the University of Colorado School of Medicine. Dr. Bajaj has substantial expertise in designing and conducting clinical trials.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

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. Ken Finn, MD (Ad hoc member)

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.

Attachment D: Caregiver Data

Data for Patients with an Active Card as of 5/31/14

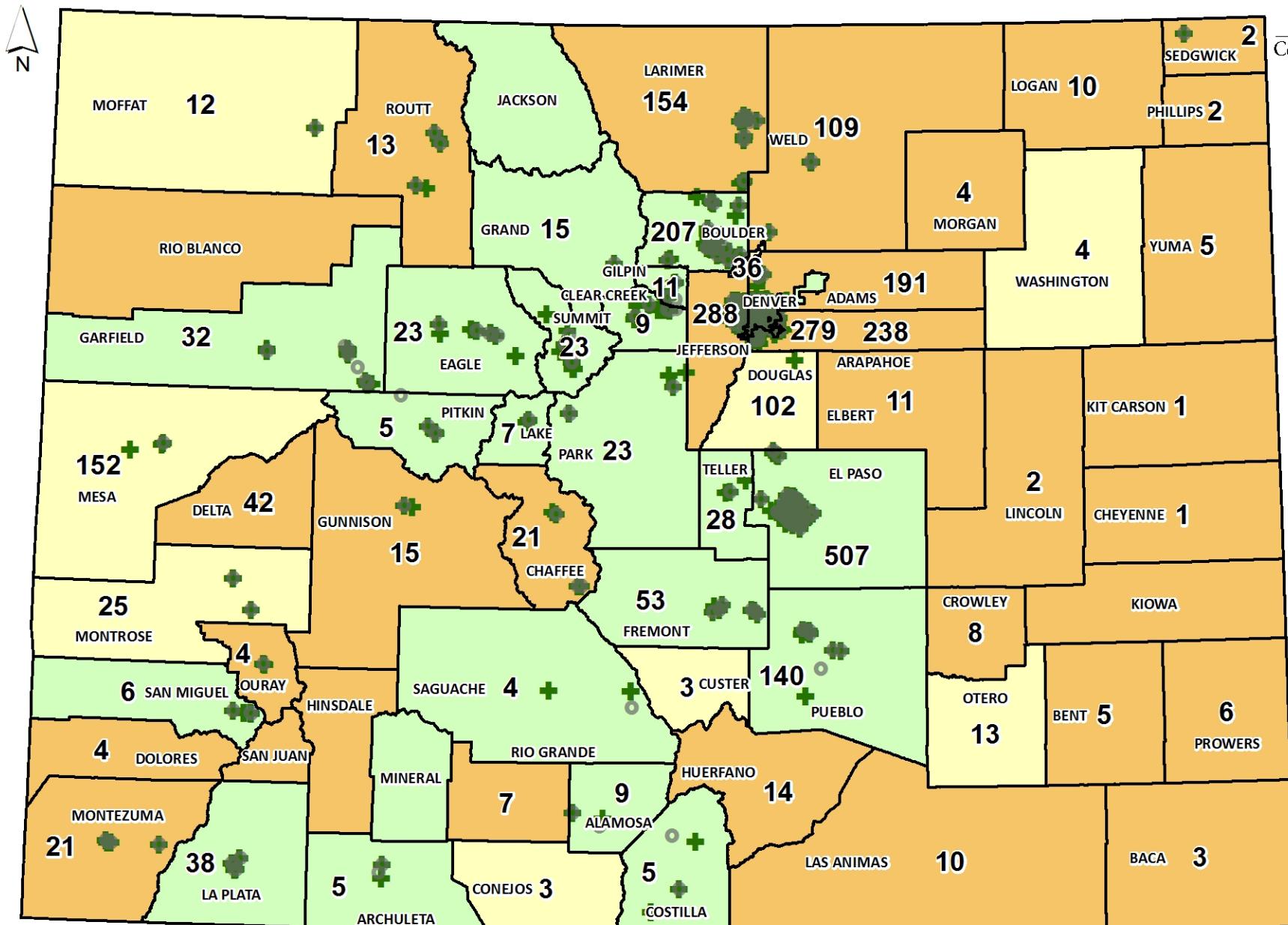
Data Generated 8-1-14

Caregiver Patient Load			
Number of Patients	Number of caregivers w/ specific patient count	% of caregivers w/specific count	# of plants if all patients had standard plant counts
1 Count	2214	76.5%	6
2 Count	353	12.2%	12
3 Count	167	5.8%	18
4 Count	107	3.7%	24
5 Count	35	1.2%	30
6 Count	12	0.4%	36
7 Count	2	0.1%	42
8 Count	1	0.03%	48
10 Count	1	0.03%	60
11 Count	2	0.07%	66
21 Count	1	0.03%	126
89 Count	1	0.03%	534
Total number of caregivers	2896		
Total number of caregivers with more than five patients	20	<0.01%	

**Attachment E: 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.					



- Licensed Medical Marijuana Centers (DOR)
- +
- Medical Marijuana Centers

- BOCC Enacted Ban/Partial Ban
- Voter Enacted Ban/Partial Ban
- Currently Allowing

The number in each county represents the number of caregivers registered with the Medical Marijuana Registry (August 2014)

STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
5CCR 1006-2 MEDICAL USE OF MARIJUANA
September 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?

Yes, the bill number is SB 14-155; rules are authorized required.

No

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

Yes

No

Does this rule incorporate materials by reference?

Yes

No

Does this rule create or modify fines or fees?

Yes

No

REGULATORY ANALYSIS
for Amendments to
5CCR 1006-2 MEDICAL USE OF MARIJUANA
September 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.
- Input was received via the stakeholder's survey. 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? X Yes _____ No. The Division provided notice on _____ August 8, 2014_____.

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 major policy issue is establishing the maximum plant count. The Department's proposal enables the Department to respond to the audit, create clarity for individuals and entities wanting to discern the differences between a caregiver and a dispensary, and do so in a manner that has minimal impact to the community. 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.

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Center for Health and Environmental Data

3 MEDICAL USE OF MARIJUANA

4 5 CCR 1006-2

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

6

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

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

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

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

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

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

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

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

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

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

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

46 C. DEFINITIONS

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

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

53 3. "COUNCIL" MEANS THE MEDICAL MARIJUANA SCIENTIFIC ADVISORY COUNCIL
54 APPOINTED BY THE EXECUTIVE DIRECTOR OF THE COLORADO DEPARTMENT OF
55 PUBLIC HEALTH AND ENVIRONMENT PER REQUIREMENTS ESTABLISHED IN SECTION
56 25-1.5-106.5, C.R.S.

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

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

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

77 Regulation 2: Application for a registry identification card

78 A. DEFINITIONS

79 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.~~

81 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.~~

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

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

98 1. The applicant's name, address, date of birth, and social security number;
99 2. The name and address of the applicant's primary care-giver or medical marijuana center,
100 applicant's if either one is designated at the time of application. Only a AT THE TIME OF
101 APPLICATION, THE PATIENT WILL INDICATE WHETHER HE OR SHE WILL UTILIZE A
102 PRIMARY CARE-GIVER OR A MEDICAL MARIJUANA CENTER. Only a Homebound or mMinor
103 patientS may must have both a primary care-giver ON RECORD. PATIENTS WHO ARE
104 DESIGNATED BY THEIR PHYSICIAN AS HOMEBOUND MAY REQUEST A WAIVER TO LIST
105 BOTH A PRIMARY CARE-GIVER AND A MEDICAL MARIJUANA CENTER. IF THE PRIMARY
106 CARE-GIVER IS NOT GROWING MEDICAL MARIJUANA FOR THE PATIENT, THE PATIENT
107 MAY DESIGNATE A and a medical marijuana center TO GROW HIS/HER MARIJUANA
108 PLANTS.

109 a. IF A CARE-GIVER IS SELECTED ON THE APPLICATION, THE PATIENT WILL
110 IDENTIFY THE CARE-GIVER'S NAME AND ADDRESS. THIS INFORMATION WILL BE
111 ENTERED INTO THE PATIENT'S RECORD AND REFLECTED ON THE
112 REGISTRATION CARD.

113 b. IF A MEDICAL MARIJUANA CENTER IS SELECTED ON THE APPLICATION, THE
114 PATIENT'S RECORD WILL REFLECT THE PATIENT HAS DESIGNATED A MEDICAL
115 MARIJUANA CENTER TO GROW HIS/HER MARIJUANA. SPECIFIC MEDICAL
116 MARIJUANA CENTER INFORMATION WILL NOT BE REFLECTED ON THE
117 REGISTRATION CARD NOR IN THE PATIENT RECORD.

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

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

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

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

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

130 A. VALID STATE OF COLORADO DRIVER'S LICENSE;

131 B. VALID STATE OF COLORADO IDENTIFICATION CARD; OR

132 C. ANY OTHER VALID GOVERNMENT-ISSUED PICTURE IDENTIFICATION THAT

133 DEMONSTRATES THAT THE HOLDER OF THE IDENTIFICATION IS A COLORADO

134 RESIDENT.

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

136 ESTABLISH RESIDENCY.

137

138 8. APPLICANTS WHO ARE UNABLE TO PROVIDE THE ABOVE-REQUIRED PROOF OF

139 IDENTIFICATION AND/OR RESIDENCY PAPERWORK MAY SUBMIT A REQUEST FOR A

140 DOCUMENTATION WAIVER.

141

142 WHEN EVALUATING A REQUEST FOR WAIVER OF THE ABOVE PROOF OF RESIDENCY

143 REQUIREMENTS, THE DEPARTMENT WILL CONSIDER THE TOTALITY OF THE VALID

144 DOCUMENTATION. SOME FACTORS THAT MAY BE CONSIDERED WHEN DETERMINING

145 RESIDENCY INCLUDE:

146

147 a. WHETHER THE APPLICANT CAN DOCUMENT THAT HIS PRIMARY OR

148 PRINCIPAL HOME OR PLACE OF ABODE IS IN COLORADO;

149

150 b. WHETHER THE APPLICANT CAN PROVIDE EVIDENCE OF COLORADO

151 BUSINESS PURSUITS, PLACE OF EMPLOYMENT, OR INCOME SOURCES,

152

153 c. WHETHER THE APPLICANT CAN DOCUMENT COLORADO RESIDENCE FOR

154 INCOME OR OTHER TAX PURPOSES;

155

156 d. IF THE APPLICANT CAN DOCUMENT THE AGE, RESIDENCE OF PARENTS,

157 SPOUSE AND CHILDREN, IF ANY;

158

159 e. THE SITUS OF THE APPLICANT'S PERSONAL AND REAL PROPERTY;

160

161 f. THE EXISTENCE OF ANY OTHER RESIDENCES OUTSIDE OF COLORADO AND

162 THE AMOUNT OF TIME SPENT AT EACH SUCH RESIDENCE;

163

164 g. ANY MOTOR VEHICLE OR VESSEL REGISTRATION, OR;

165

166 h. RECENT PROPERTY TAX RECEIPTS, RECENT INCOME TAX RETURNS WHERE

167 A COLORADO MAILING ADDRESS IS USED AS THE PRIMARY ADDRESS,

168 CURRENT VOTER REGISTRATION CARDS, OR OTHER SIMILAR PUBLIC

169 RECORDS.

170

171 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 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:

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

173

174 2. Written documentation from two of the applicant's physicians that the applicant has been

175 diagnosed with a debilitating medical condition as defined in regulation six and each physician's

176 conclusion that the applicant might benefit from the medical use of marijuana;

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

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

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

187 **6. INDICATE IF A MEDICAL MARIJUANA CENTER HAS BEEN DESIGNATED TO GROW
188 FOR THE PATIENT.**

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

194 D. E. A patient may change his or her primary care-giver ~~WITH THE DEPARTMENT or medical~~
195 ~~marijuana center~~ no more than once per month. A patient may change his or her primary care-giver ~~or~~
196 ~~medical marijuana center~~ by submitting such information on the form and in the manner as directed by
197 the department within ten days of the change occurring. **THE DEPARTMENT DOES NOT**
198 **PROCESS PATIENT REQUESTS TO CHANGE HIS OR HER DESIGNATED MEDICAL**
199 **MARIJUANA CENTER; A PATIENT WISHING TO CHANGE HIS OR HER DESIGNATED**
200 **MEDICAL MARIJUANA CENTER SHOULD REFERENCE THE REQUIREMENTS**
201 **ESTABLISHED BY THE DEPARTMENT OF REVENUE'S MARIJUANA ENFORCEMENT**
202 **DIVISION.**

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

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

208 2. If the application is not notarized; or

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

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

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

213 1. The physician recommendation is falsified;

214 2. Any information on the application is falsified;

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

217 4. The applicant is not a Colorado resident;

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

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

223 G. **H.** The department may revoke a registry identification card for one year if the patient has been found
224 to have willfully violated the provisions of article xviii, section 14 of the Colorado Constitution or C.R.S. §
225 25-1.5-106.

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

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

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

235 I. **J.** Appeals. If the department denies an application or, suspends or, revokes a registry identification
236 card, the department shall provide the applicant/patient with notice of the grounds for the denial,
237 suspension, or revocation, and shall inform the patient of the patient's right to request a hearing. 4. A
238 request for hearing shall be submitted to the department in writing within thirty (30) calendar days from
239 the date of the postmark on the notice.

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

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

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

247 *****

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

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

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

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

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

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

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

275 a. If there are no peer-reviewed published studies of randomized controlled studies NOR
276 WELL-DESIGNED OBSERVATIONAL STUDIES showing efficacy in humans for use of
277 medical marijuana for the condition that is the subject of the petition;

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

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

287 d. If a majority of the ad hoc medical advisory panel recommends denial of the petition in
288 accord with paragraph (3) of this section D.

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

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

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

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

303 b. The department shall establish an ad hoc A-medical MARIJUANA SCIENTIFIC
304 advisory panel COUNCIL to will review petitions TO ADD DEBILITATING MEDICAL
305 CONDITIONS if the CONDITIONS FOR DENIAL SET FORTH IN PARAGRAPHS
306 (2)(A),(B) AND (C) OF THIS SECTION D ARE NOT MET. WHEN REVIEWING
307 PETITIONS TO ADD DEBILITATING MEDICAL CONDITIONS TO THE REGISTRY,
308 THE AD HOC MEMBER OF THE COUNCIL MAY BE REPLACED BY AN AD HOC
309 PHYSICIAN IN THE FIELD RELEVANT TO THE PETITION. SUCH INDIVIDUAL MAY
310 BE RECOMMENDED BY THE PETITIONER.

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

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

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

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

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

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

330 d. e. ~~Department requests for rulemaking hearings on petitions to add debilitating~~
331 ~~medical conditions~~. Within (120) days of receipt of a petition to add a debilitating medical
332 condition, the department shall petition the board for a rulemaking hearing to consider
333 adding the condition to the list of debilitating medical conditions if the COUNCIL ~~ad hoc~~
334 medical advisory panel recommends approval of the petition to add the condition.

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

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

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

340

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

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

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

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

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

353 1. The information submitted by the patient applicant;

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

355 3. COUNTY-WIDE PROHIBITIONS ON MEDICAL MARIJUANA CENTERS;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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393 Regulation 12: Patient Responsibilities.

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

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

408 C. A patient shall not:

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

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

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

415 4. Possess medical marijuana or otherwise engage in the use of medical marijuana in or on the
416 grounds of a school or in a school bus;

417 5. Engage in the use of medical marijuana while:

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

419 b. Subject to a sentence to incarceration;

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

421 d. As otherwise ordered by the court.

422 6. Operate, navigate, or be in actual physical control of any vehicle, aircraft, or motorboat while

423 under the influence of medical marijuana; or

424 7. Use medical marijuana if the patient does not have a debilitating medical condition as

425 diagnosed by the person's physician in the course of a bona fide physician-patient relationship

426 and for which the physician has recommended the use of medical marijuana.

427 D. A patient who no longer has a debilitating medical condition shall return his or her registry

428 identification card to the department within twenty-four hours of receiving such diagnosis by his or her

429 physician.

430 E. A patient shall notify the department if convicted of a criminal offense under article 18 of title 18,

431 C.R.S., sentenced or ordered by a court to drug or substance abuse treatment, or sentenced to the

432 division of youth corrections. The patient shall be subject to immediate renewal of his/her registry

433 identification card. Such patient may only reapply with a new physician recommendation from a physician

434 with whom the patient has a bona fide relationship.

435 1. The patient shall remit the registry card to the department within 24 hours of the

436 conviction/sentence/court order.

437 2. The patient may complete and submit a new application for a registry card including a new

438 recommendation from a physician with a bona fide relationship.

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

440 consume medical marijuana.

441 *****

442 REGULATION 14: COLORADO MEDICAL MARIJUANA RESEARCH GRANT PROGRAM

443 A. PROCEDURES FOR GRANT APPLICATION TO THE GRANT PROGRAM

444 1. GRANT APPLICATION CONTENTS.

445 a. AT A MINIMUM, ALL APPLICATIONS SHALL BE SUBMITTED TO THE

446 DEPARTMENT IN ACCORDANCE WITH THESE RULES AND SHALL CONTAIN THE

447 FOLLOWING INFORMATION:

448 i. A DESCRIPTION OF KEY PERSONNEL, INCLUDING CLINICIANS,

449 SCIENTISTS, OR EPIDEMIOLOGISTS AND SUPPORT PERSONNEL,

450 DEMONSTRATING THEY ARE ADEQUATELY TRAINED TO CONDUCT THIS

451 RESEARCH.

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

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

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

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

466 2. TIMELINES FOR GRANT APPLICATION.

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

469 B. CRITERIA FOR SELECTING ENTITIES

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

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

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

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

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

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

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

491 C. GRANTEE REPORTING

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

494 a. QUARTERLY PROGRESS REPORTS

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

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

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

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

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