

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Center for Health and Environmental Data

MEDICAL USE OF MARIJUANA

5 CCR 1006-2

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

Adopted by the Board of Health on November 18, 2015

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. A primary caregiver may have one or more of the following relationships:
 - a. A parent of a child as described by section (6) (e) of section 14 of article xviii of the Colorado Constitution and anyone who assists that parent with caregiver responsibilities, including cultivation and transportation;
 - b. An advising caregiver who advises a patient on which medical marijuana products to use and how to dose them and does not possess, provide, cultivate, or transport marijuana on behalf of the patient;
 - c. A transporting caregiver who purchases and transports marijuana to a patient who is homebound; or
 - d. A cultivating caregiver who grows marijuana for a patient.
 6. “Significant responsibility for managing the well-being of a patient” means that the caregiver is involved in basic or instrumental activities of daily living. Cultivating or transporting marijuana and the act of advising a patient on which medical marijuana products to use and how to dose them constitutes a “significant responsibility.”

Regulation 2: Application for a registry identification card

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

1. The applicant's name, address, date of birth, and social security number;
2. At the time of application, the patient will indicate whether he or she will utilize a primary care-giver or a medical marijuana center. Minor patients must have a primary care-giver on record. Patients who are designated by their physician as homebound may request a waiver to list both a primary care-giver and a medical marijuana center. If the primary care-giver is not growing medical marijuana for the patient, the patient may designate a medical marijuana center to grow his/her marijuana plants.
 - a. If a care-giver is selected on the application, the patient will identify the care-giver's name and address. This information will be entered into the patient's record and reflected on the registration card.
 - b. If a medical marijuana center is selected on the application, the patient's record will reflect the patient has designated a medical marijuana center to grow his/her marijuana. Specific medical marijuana center information will not be reflected on the registration card nor in the patient record.
3. Written documentation from the applicant's physician that the applicant has been diagnosed with a debilitating medical condition as defined in regulation 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. When evaluating a request for waiver of the above proof of residency requirements, the department will consider the totality of the valid documentation. Some factors that may be considered when determining residency include:
 - a. Whether the applicant can document that his primary or principal home or place of abode is in Colorado;

- b. Whether the applicant can provide evidence of Colorado business pursuits, place of employment, or income sources,
 - c. Whether the applicant can document Colorado residence for income or other tax purposes;
 - d. If the applicant can document the age, residence of parents, spouse and children, if any;
 - e. The situs of the applicant's personal and real property;
 - f. The existence of any other residences outside of Colorado and the amount of time spent at each such residence;
 - g. Any motor vehicle or vessel registration, or;
 - h. Recent property tax receipts, recent income tax returns where a Colorado mailing address is used as the primary address, current voter registration cards, or other similar public records.
- 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 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 (3) 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. Indicate if a medical marijuana center has been designated to grow for the patient.
- C. 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 A and B of this regulation.

- D. A patient may change his or her primary care-giver with the department no more than once per month. A patient may change his or her primary care-giver by submitting such information on the form and in the manner as directed by the department within ten days of the change occurring. The department does not process patient requests to change his or her designated medical marijuana center; a patient wishing to change his or her designated medical marijuana center should reference the requirements established by the department of revenue's marijuana enforcement division.
- E. 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. The physician(s) is/are not eligible to recommend the use of marijuana.
 3. An applicant shall have (60) days from the date the department mails the rejected application to make corrections and resubmit the application.
- F. 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. 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. 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. 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. 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. 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. If a request for a hearing is made, the hearing shall be conducted in accordance with the State Administrative Procedure Act, § 24-4-101, et seq., C.R.S.
 3. 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.

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

- A. The department shall verify medical information contained in the patient's application within thirty days of receiving the application. Verification of medical information shall consist of determining that there is documentation stating the applicant has a current diagnosis with a debilitating medical condition as defined in regulation six, by a physician who has a current active, unrestricted and unconditioned license as defined in Regulation 8 to practice medicine issued by the State of Colorado, which license is in good standing, and who has a bona fide physician patient relationship with the patient as defined in regulation eight.
- B. No more than five days after verifying medical information of the applicant, the department shall issue a serially numbered registry identification card to the patient. The card shall state the following:
 - i) The patient's name, address, date of birth, and social security number;
 - ii) That the patient's name has been certified to the department as a person with a debilitating medical condition, whereby the person may address such condition with the medical use of marijuana;
 - iii) The date of issuance of such card and the date of expiration, which shall be one year from the date of issuance;
 - iv) The name and address of the patient's primary care-giver, if any is designated at the time of application;
 - v) How to notify the department of any change in name, address, medical status, physician, or primary care-giver.
- C. Except for minor applicants, where the department fails within thirty-five days of receipt of application to issue a registry identification card or fails to issue verbal or written notice of denial of such application, the patient's application for such card will be deemed to have been approved. "Receipt" shall be deemed to have occurred upon delivery to the department or deposit in the United States mail. No application shall be deemed received prior to June 1, 2001.

- D. The department shall deny the application if it determines that information has been falsified or it cannot verify the medical information as provided in paragraph A of this regulation. A patient whose application has been denied by the department may not reapply during the six months following the date of denial. The denial of a registry identification card shall be considered a final agency action.
- E. In addition to any other penalties provided by law, the department shall revoke for a period of one year the registry identification card of any patient found to have willfully violated the provisions of Section 14 of Amendment 20 of the Colorado Constitution or the implementing legislation of Section 14.

Regulation 4: Change in applicant information

- A. When there has been a change in the name, address, physician or primary care-giver of a patient who has been issued a registry identification card, that patient must notify the department within ten days by submitting a completed Change of Address or Care-giver form as prescribed by the Department. A patient who has not designated a primary care-giver at the time of application to the department may do so in writing at any time during the effective period of the registry identification card, and the primary care-giver may act in this capacity after such designation. The Department shall not issue a new registry identification card to the patient on the sole basis of a new or change of primary care-giver.
- B. A patient who no longer has a debilitating medical condition as defined in regulation six shall return his registry identification card to the department within twenty-four hours of receiving such information by his or her physician.

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

- A. Authorized employees of state or local law enforcement agencies shall be granted access to the information contained within the department's registry only for the purpose of verifying that an individual who has presented a registry identification card to a state or local law enforcement official is lawfully in possession of such card. The department shall report to authorized state or local law enforcement officials whether a patient's registry identification card has been suspended because the patient no longer has a debilitating medical condition.
- B. Authorized employees of state or local law enforcement agencies shall immediately notify the department when any person in possession of a registry identification card has been determined by a court of law to have willfully violated the provisions of this section 14 of the Colorado constitution or its implementing legislation, or has pled guilty to such offense.

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.

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- 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 nor 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.
 3. If the conditions of denial set forth in paragraph (2) are not met, the department shall petition the board within 90 days of receipt of a petition for a rulemaking hearing to consider adding the condition to the list of debilitating medical conditions.
 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

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

- A. Application fee. Effective February 1, 2014, the department shall collect fifteen dollars from each applicant at the time of application to pay for the direct and indirect costs to administer the medical use of marijuana program, unless the applicant meets the criteria set forth in section (b) of this Regulation (7) establishing indigence. Such fee shall not be refundable to the applicant if the application is denied or revoked or if the patient no longer has a debilitating medical condition. The amount of the fee shall be evaluated annually by the department to ensure compliance with the applicable statutes and the fee meets the actual Medical Marijuana Registry expenses. The department shall propose modifications to the board, as appropriate. If the patient provides updated information at any time during the effective period of the registry identification card, the department shall not charge a fee to modify the registry information concerning the patient.
- B. Indigence fee waiver. Any individual submitting an application for the registry may request an indigence fee waiver if he or she submits at the time of application a copy of the applicant's state tax return certified by the department of revenue that confirms that the applicant's income does not exceed one hundred eighty-five percent of the federal poverty line, adjusted for family size.
- C. Notification of indigent status. Individuals who meet the indigence standard after they have been approved for the medical marijuana registry may complete a form, to be determined by the department, notifying the department of their status and supplying a copy of the applicant's state tax return certified by the department of revenue that confirms that the applicant's income does not exceed one hundred eighty-five percent of the federal poverty line, adjusted for family size. Upon receipt and confirmation of the information, the department shall issue a new medical marijuana registry card for the remaining term of the current card noting said indigent status for tax exemption purposes.

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

- A. **Physician Requirements.** A physician who certifies a debilitating medical condition for an applicant to the medical marijuana program shall comply with all of the following requirements:
 - 1. **Colorado license to practice medicine.** The physician shall have a valid, unrestricted Colorado license to practice medicine, which license is in good standing.
 - a. for the purposes of certifying a debilitating medical condition of an applicant and recommending the use of medical marijuana for the medical marijuana program, "in good standing" means:
 - i. The physician holds a doctor of medicine or doctor of osteopathic medicine degree from an accredited medical school.
 - ii. The physician holds a valid license to practice medicine in Colorado that does not contain a restriction or condition that prohibits the recommendation of medical marijuana or for a license issued prior to July 1, 2011, a valid, unrestricted and unconditioned; and
 - iii. The physician has a valid and unrestricted United States Department of Justice federal drug enforcement administration controlled substances registration.

2. **Bona fide physician patient relationship.** A physician who meets the requirements in subsection A.1 of this Regulation 8 and who has a bona fide physician-patient relationship with a particular patient may certify to the state health agency that the patient has a debilitating medical condition and that the patient may benefit from the use of medical marijuana. If the physician certifies that the patient would benefit from the use of medical marijuana based on a chronic or debilitating disease or medical condition, the physician shall specify the chronic or debilitating disease or medical condition and, if known, the cause or source of the chronic or debilitating disease or medical condition.
 - a. “Bona fide physician-patient relationship”, for purposes of the medical marijuana program, means:
 - i. A physician and a patient have a treatment or counseling relationship, in the course of which the physician has completed a full assessment of the patient's medical history and current medical condition, including an appropriate personal physical examination;
 - ii. The physician has consulted with the patient with respect to the patient's debilitating medical condition before the patient applies for a registry identification card; and
 - iii. The physician is available to or offers to provide follow-up care and treatment to the patient, including but not limited to patient examinations, to determine the efficacy of the use of medical marijuana as a treatment of the patient's debilitating medical condition.
 - b. A physician making medical marijuana recommendations shall comply with generally accepted standards of medical practice, the provisions of the medical practice act, § 12-36-101 *et seq.*, C.R.S, and all Colorado Medical Board rules.
 - c. The “appropriate personal physical examination” required by paragraph A.2.a.i of this Regulation 8 may not be performed by remote means, including telemedicine.
3. **Medical records.** The physician shall maintain a record-keeping system for all patients for whom the physician has recommended the medical use of marijuana. Pursuant to an investigation initiated by the Colorado medical board, the physician shall produce such medical records to the Colorado Medical Board after redacting any patient or primary caregiver identifying information.
4. **Financial prohibitions.** A physician shall not:
 - a. Accept, solicit, or offer any form of pecuniary remuneration from or to a primary caregiver, distributor, or any other provider of medical marijuana;
 - b. Offer a discount or any other thing of value to a patient who uses or agrees to use a particular primary caregiver, distributor, or other provider of medical marijuana to procure medical marijuana;
 - c. Examine a patient for purposes of diagnosing a debilitating medical condition at a location where medical marijuana is sold or distributed; or
 - d. Hold an economic interest in an enterprise that provides or distributes medical marijuana if the physician certifies the debilitating medical condition of a patient for participation in the medical marijuana program.

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- B. **Reasonable cause for referral of a physician to the Colorado Medical Board.** For reasonable cause, the department may refer a physician who has certified a debilitating medical condition of an applicant to the medical marijuana registry to the Colorado Medical Board for potential violations of sub-paragraphs 1, 2, and 3 of paragraph A of this rule.
- C. **Reasonable cause for department sanctions concerning physicians.** For reasonable cause, the department may sanction a physician who certifies a debilitating medical condition for an applicant to the medical marijuana registry for violations of paragraph A.4 of this rule. Reasonable cause shall include, but not be limited to:
1. The physician is housed onsite and/or conducts patient evaluations for purposes of the medical marijuana program at a location where medical marijuana is sold or distributed, such as a medical marijuana center, optional grow site, medically infused products manufacturer, by a primary care-giver, or other distributor of medical marijuana.
 2. A physician who holds an economic interest in an entity that provides or distributes medical marijuana, such as a medical marijuana center, an infused products manufacturer, an optional grow site, a primary care-giver, or other distributor of medical marijuana.
 3. The physician accepts, offers or solicits any form of pecuniary remuneration from or to a primary care-giver, medical marijuana center, optional grow site, medically infused product manufacturer, or any other distributor of medical marijuana.
 4. The physician offers a discount or any other thing of value, including but not limited to a coupon for reduced-price medical marijuana or a reduced fee for physician services, to a patient who agrees to use a particular medical marijuana center, primary care-giver, or other distributor of medical marijuana.
- D. **Sanctions.** For reasonable cause, the department may propose any of the following sanctions against a physician:
1. Revocation of the physician's ability to certify a debilitating medical condition and recommend medical marijuana for an applicant to the medical marijuana registry; or
 2. Summary suspension of the physician's ability to certify a debilitating medical condition or recommend medical marijuana for an applicant to the medical marijuana registry when the department reasonably and objectively believes that a physician has deliberately and willfully violated section 14 of article xviii of the state constitution or § 25-1.5-106, C.R.S. and the public health, safety and welfare imperatively requires emergency action.
- E. **Appeals.** If the department proposes to sanction a physician pursuant to paragraph c of this rule, the department shall provide the physician with notice of the grounds for the sanction and shall inform the physician of the physician'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 physician 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 physician does not request a hearing in writing within thirty (30) calendar days from the date of the notice, the physician is deemed to have waived the opportunity for a hearing.

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

- A. A patient who designates a primary care-giver for him or herself cannot also be a primary care-giver to another patient.
- B. A cultivating or transporting caregiver shall be listed as a primary caregiver for no more than five patients in the medical marijuana registry at any given time unless a waiver as set forth in Regulation Ten has been granted for exceptional circumstances.
- C. An existing primary care-giver may indicate to the department at the time of registration on a form to be developed by the department if the primary care-giver is available to serve more patients. An individual who is not a registered primary care-giver, but who would like to become one may submit contact information to the registry. The primary care-giver or prospective primary care-giver shall waive confidentiality to allow release of contact information to physicians or registered patients only. The department may provide the information but shall not endorse or vouch for any primary care-giver or prospective primary care-giver.
- D. A primary care-giver if asked by law enforcement shall provide a list of registry identification numbers for each patient. If a waiver has been granted for a cultivating or transporting caregiver to serve more than five patients, this will be noted on the department record of cultivating and transporting care-givers and will be available for verification to law enforcement upon inquiry to the department.
- E. A primary care-giver shall have his/her primary registration card available on his/her person at all times when in possession of marijuana and produce it at the request of law enforcement. The only exception to this shall be 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 not yet issued or denied a registry identification card. A copy of the patient's application along with proof of the date of submission shall be in the primary care-giver's possession at all times that the primary care-giver is in possession of marijuana. The primary care-giver may redact all confidential patient information from the application other than the patient's name and date of birth.
- F. A patient may only have one primary care-giver at a time.
- G. A designated primary care-giver shall not delegate the responsibility of provision of medical marijuana for a patient to another person.
- H. A primary care-giver shall not join together with another primary care-giver for the purpose of growing marijuana. Any marijuana grows by a care-giver shall be physically separate from grows by other primary care-givers and licensed growers or medical marijuana centers, and a primary care-giver shall not grow marijuana for another primary care-giver. If two or more care-givers reside in the same household and each grows marijuana for their registered patients, the marijuana grows must be maintained in such a way that the plants and/or ounces grown and or maintained by each primary care-giver are separately identified from any other primary care-givers plants and/or ounces.
- I. A primary care-giver shall not establish a business to permit patients to congregate and smoke or otherwise consume medical marijuana.
- J. A primary care-giver 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 except when the possession or use occurs in accordance with a school district board policy established pursuant to § 22-1-119.3, C.R.S.;
 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; or c. In a vehicle, aircraft, or motorboat;
 6. Operate, navigate, or be in actual physical control of any vehicle, aircraft, or motorboat while under the influence of medical marijuana; or
 7. Provide 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.
- K. A primary care-giver may charge a patient no more than the cost of cultivating or purchasing the medical marijuana, and may also charge for care-giver services. Such care-giver charges shall be appropriate for the care-giver services rendered and reflect market rates for similar care-giver services and not costs associated with procuring the marijuana.
- L. A primary care-giver shall have significant responsibility for managing the well-being of a patient with a debilitating condition.

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.
- 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. The proximity of medical marijuana centers to the patient;
 5. Whether granting the waiver would either benefit or adversely affect the health, safety or welfare of the patient; and
 6. 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.

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

- A. If the physician recommending the marijuana checks on the recommending form that the patient is homebound, a waiver will be granted allowing a designated primary care-giver to transport marijuana from a medical marijuana center to the patient.
- B. The term for the waiver shall be the same as the effective dates of the patient's registry identification card.
- C. 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.
- D. The department may revoke a waiver if it determines that any of the following are met:
 1. The waiver jeopardizes the health, safety and welfare of patients;
 2. The patient applicant has provided false or misleading information in the application;
 3. The patient applicant 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.
- E. Primary care-givers for minors shall have a waiver for transportation automatically granted as part of a successful application process if the patient application indicates that the minor's primary care-giver will be purchasing medical marijuana from a medical marijuana center. The term of the waiver will coincide with the term of the registry identification card.
- F. The department will provide notice of the revocation of the waiver to the patient and the primary care-giver at the time the waiver is revoked.
- G. Appeals. If the department proposes to deny, condition, revoke or suspend a waiver for a primary care-giver to deliver medical marijuana products to a homebound patient, 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.

Regulation 12: Patient Responsibilities.

- A. A patient shall provide his/her care-giver 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, 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 except when the possession or use occurs in accordance with a school district board policy established pursuant to § 22-1-119.3, C.R.S.;
 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.

Regulation 13: Subpoenas for Registry Information

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

Regulation 14: Colorado medical research grant program

- A. Procedures for grant application to the grant program
1. In order to ensure objectivity in evaluating research proposals, the grant program shall establish a scientific advisory council (council).
 - a. The council shall perform all of the following duties:
 - i. Provide policy guidance in the creation and implementation of the research grant program and in scientific oversight and review.
 - ii. Objectively evaluate research proposals and provide a peer review process that guards against funding research that is biased in favor of or against particular outcomes.
 - iii. Submit recommendations to the department and the state board of health for recommended grant recipients, grant amounts, and grant duration.

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2. 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.
 3. Timelines for grant application.
 - a. Absent approval from the board of health, the department will seek applications no more than three times per year.
 - b. The department will notify prospective applicants of the opportunity to apply.
 - c. Prospective applicants will have a minimum of thirty days to apply.
 - d. Applications will be reviewed within 120 days of submission and referral of recommended applications to the board of health will be within 180 days of submission.
- 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.

Editor's Notes

History

Regulation 7 eff. 07/30/2007.

Entire rule eff. 08/30/2009.

Regulation 2.A(iii) repealed as emer. rule eff. 11/03/2009; expired 02/03/2010.

Regulation 7 eff. 11/30/2010.

Regulation 6 eff. 03/02/2011.

Regulations 3.A, 8 eff. 04/30/2011.

Regulations 1, 2, 9, 10, 11, 12, 13 eff. 07/30/2011.

Regulations 7, 8.A eff. 12/30/2011.

Regulation 7.A eff. 02/01/2014.

Entire rule eff. 11/14/2014.

Regulations 2.A, 2.B., 2.B.5, 2.I, 2.I.2, 4.A, 6.D.2.c, 6.D.3, 14.A eff. 09/14/2015. Regulation 6.D.2.d repealed eff. 09/14/2015.

Regulations 1.C.5-1.C.6, 2.E, 9.B, 9.D, 9.F, 9.J.4, 9.L, 12.C.4 eff. 01/14/2016.

Annotations

A Denver district court (Case No: 2007 CV 6089, LaGoy v. Ritter, et al) has enjoined the enforcement of the emergency rule repealing Regulation 2.A.iii eff. 11/03/2009. Per agency request, prior Regulation 2.A.iii, eff. 08/30/2010, has been restored to its place in 5 CCR 1006-2, in order to effectuate the intent of the Court and the parties that the prior regulation be reinstated.

Rules 6.D.3. and 14.A.2. (adopted 09/16/2014) were not extended by Senate Bill 15-100 and therefore expired 05/15/2015.