COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2018 Sunset Review:

Medical Marijuana Program

October 15, 2018

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2018

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Since that time, Colorado's sunset process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), directs the Department of Regulatory Agencies to:

- Conduct an analysis of the performance of each division, board or agency or each function scheduled for termination; and

- Submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. Accordingly, COPRRR has completed the evaluation of the medical marijuana program administered by the Colorado Department of Public Health and Environment (CDPHE). I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2019 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Section 106 of Article 1.5 of Title 25, C.R.S. The report also discusses the effectiveness of the staff of CDPHE in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Marguerite Salazar
Executive Director

COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2018 Sunset Review
Medical Marijuana Program

SUMMARY

What is the medical marijuana program?
The medical marijuana program at the Colorado Department of Public Health and Environment (CDPHE) implements various aspects of Amendment 20 to the state's constitution, including the establishment of the medical marijuana registry for patients and caregivers, the standards for creating a bona fide physician-patient relationship and the creation of a process whereby the Colorado Board of Health (Board of Health) can add to the list of debilitating conditions that make patients eligible to use medical marijuana. The program also maintains the marijuana laboratory testing reference library (as required by the Medical Marijuana Code) and assists the Executive Director of the Department of Revenue in approving marijuana testing facilities. The Colorado Medical Marijuana Code creates the regulatory structure for the state's commercial medical marijuana industry and is not part of this sunset review.

Why is the medical marijuana program necessary?
Amendment 20 to the state's constitution requires the Governor to designate a "state health agency" to establish and maintain the medical marijuana registry. CDPHE is that agency, and the medical marijuana program provides the structure for implementing Amendment 20 and other medical marijuana-related policy objectives.

Who is affected by the medical marijuana program?
As of the end of 2017, there were 93,372 registered medical marijuana patients and 2,507 registered caregivers, of which approximately 2,000 were voluntarily registered. As of June 2018, approximately 390 physicians had obtained accounts with CDPHE enabling them to recommend medical marijuana to patients.

How is it operated?
To legally grow or obtain medical marijuana, a person must first establish a bona fide physician-patient relationship with a licensed physician. The physician must: 1) diagnose the patient with a debilitating or disabling medical condition; 2) find that the patient would likely benefit from the use of medical marijuana; and 3) upload a recommendation for medical marijuana into the medical marijuana registry. The patient then registers with the registry and obtains a registry identification card that can be shown to law enforcement to confirm the person's status as a patient, and to caregivers and medical marijuana centers to obtain medical marijuana.

What does it cost?
In fiscal year 16-17, CDPHE dedicated 18.6 full-time equivalent (FTE) employees and spent approximately $2.03 million on administering and maintaining the medical marijuana registry. CDPHE also dedicated 7.0 FTE and spent approximately $1.7 million on assisting the Executive Director of the Department of Revenue with approving marijuana testing facilities.

What disciplinary activity is there?
Since 2016, 19 patient registrations have been revoked. Since January 2017, three physicians have had their access to CDPHE's online registration system restricted due to their medical licenses being disciplined by the Colorado Medical Board.

Key Recommendations

Continue the medical marijuana program at CDPHE for nine years, until 2028.
Amendment 20 requires the creation of a medical marijuana registry, requires the Governor to designate a "state health agency" to maintain that registry and requires the General Assembly to pass implementing legislation. The medical program at CDPHE accomplishes all of these tasks. Therefore, the General Assembly should continue it for nine years, until 2028.

Clarify that medical marijuana registry identification cards are subject to immediate revocation, not renewal, upon a patient's conviction for violating the state Controlled Substances Act and sentencing to substance abuse treatment or the Division of Youth Services, and clarify that application for renewal is permissive, not mandatory.
Statute currently stipulates that the registry card of any patient who is convicted of a crime or who is sentenced to substance abuse treatment or the Division of Youth Services is subject to immediate renewal and requires the patient to apply for renewal. The clear intent of this provision is to provide CDPHE the opportunity to immediately review a patient's application upon the occurrence of an articulated triggering event. Therefore, the General Assembly should clarify this process.

Clarify that medical marijuana registry information pertaining to patients with disabling medical conditions is provided the same confidentiality protections as information pertaining to patients with debilitating medical conditions.
Amendment 20 addresses the confidentiality of information contained in the medical marijuana registry. However, since the constitution speaks only to debilitating medical conditions (those articulated in the constitution), as opposed to disabling medical conditions (those articulated in statute), some interpret the constitution's protections as applying only to debilitating conditions. Therefore, the statute should be clarified so that patient information is protected the same, regardless of the type of qualifying condition.

Methodology

As part of this review, Colorado Office of Policy, Research and Regulatory Reform staff interviewed staff of CDPHE and other stakeholders, attended a meeting of the Scientific Advisory Council and reviewed Colorado statutes and rules.

Major Contacts Made During This Review

Cannabis Clinicians Colorado
Cannabis Consumers Coalition
Cannabis Patients Alliance
CannAbility Foundation
City and County of Denver
City of Colorado Springs
Colorado Attorney General's Office
Colorado Department of Public Health & Environment
Colorado Department of Revenue
Colorado District Attorneys' Council
Colorado Psychiatric Association
Colorado Municipal League
COPIC
Law Enforcement Action Partnership
Smart Colorado
Southern Colorado Cannabis Coalition
The Behavioral Partnership
Veterans for Medical Cannabis Acces

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are prepared by:
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

[1] Criteria may be found at § 24-34-104, C.R.S.

- Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subparagraph (i) of paragraph (a) of subsection (8) of this section shall include data on the number of licenses or certifications that were denied, revoked, or suspended based on a disqualification and the basis for the disqualification; and
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR's website at: www.dora.colorado.gov/opr.

The functions of the Colorado Department of Public Health and Environment (CDPHE), as enumerated in Section 106 of Article 1.5 of Title 25, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2019, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of CDPHE's administration of the medical marijuana program pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the medical marijuana program should be continued and to evaluate the performance of CDPHE. During this review, CDPHE must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff interviewed staff of CDPHE and other stakeholders, attended a meeting of the Scientific Advisory Council and reviewed Colorado statutes and rules.

Profile of Medical Marijuana

The term "marijuana" refers to the "dried leaves, flowers, stems and seeds of the *Cannabis sativa* or *Cannabis indica* plant."[2]

The marijuana plant contains over 100 chemicals called cannabinoids,[3] which are similar to endocannabinoids. Endocannabinoids are produced by the human body and play a role in regulating pleasure, memory, thinking, concentration, body movement, sensory and time perception, appetite and pain.[4] When cannabinoids are ingested, they act on specific molecular targets on brain cells, called cannabinoid receptors, which can overactivate the endocannabinoid system, resulting in the "high" and other effects users often experience.[5]

Of the over 100 cannabinoids known to exist, only two are of therapeutic interest—cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC). These two cannabinoids are found in varying ratios in the marijuana plant. THC, the more widely known of the two because of its mind-altering effects, not only stimulates appetite and reduces nausea, but it may also decrease pain, inflammation and spasticity. CBD is non-psychoactive and may be useful in reducing pain and inflammation, controlling epileptic seizures and possibly even treating mental illness and addictions.[6]

As a result of these characteristics, medical marijuana is most typically used to provide relief from muscle spasms and chronic pain, reduce interlobular pressure inside the eye, suppress nausea and stimulate appetite. Patients suffering from acquired immune deficiency syndrome (AIDS), glaucoma, cancer, multiple sclerosis, epilepsy, chronic pain, anxiety, depression and obsession are most frequently associated with medical marijuana use.[7]

Colorado's experience with medical marijuana began in earnest on December 28, 2000, when Amendment 20 took effect. In short, Amendment 20 authorized those with certain debilitating medical conditions to grow, possess and use limited amounts of marijuana.[8] Amendment 20 envisioned patients either growing their own marijuana (up to six plants, or more if medically necessary)[9] or forming relationships with primary caregivers who grow the plants for their patients and who bear "significant responsibility for managing the well-being of" their patients.[10]

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[2] National Institute on Drug Abuse. *Marijuana: What is marijuana?* Retrieved May 9, 2018, from www.drugabuse.gov/publications/drugfacts/marijuana
[3] National Institute on Drug Abuse. *Marijuana as Medicine: What is medical marijuana?* Retrieved May 9, 2018, from www.drugabuse.gov/publications/drugfacts/marijuana-medicine
[4] National Institute on Drug Abuse. *Marijuana as Medicine: What is medical marijuana?* Retrieved May 9, 2018, from www.drugabuse.gov/publications/drugfacts/marijuana-medicine
[5] National Institute on Drug Abuse. *Marijuana: What is marijuana?* Retrieved May 9, 2018, from www.drugabuse.gov/publications/drugfacts/marijuana
[6] National Institute on Drug Abuse. *Marijuana as Medicine: What is medical marijuana?* Retrieved May 9, 2018, from www.drugabuse.gov/publications/drugfacts/marijuana-medicine
[7] Disabled World. *Medical Marijuana: Legalities & Health Condition Uses*. Retrieved May 9, 2018, from www.disabled-world.com/medical/pharmaceutical/marijuana
[8] Colo. Const. Art. XVIII, § 14.
[9] Colo. Const. Art. XVIII, § 14(4).
[10] Colo. Const. Art. XVIII, § 14(1)(f).

Colorado's medical marijuana environment has evolved dramatically in the years since Amendment 20's passage. Although the intimate, one-on-one relationship of the primary caregiver and patient continues, it has been subsumed by the commercialization of marijuana in the state.

Patients can now obtain medical marijuana from medical marijuana centers (historically known as dispensaries). Many medical marijuana centers will provide discounts or special pricing to those patients who designate a particular medical marijuana center as their "primary center." The cultivation facilities associated with these medical marijuana centers, in turn, may legally grow marijuana for their registered patients.

Regardless of whether a patient grows his or her own medical marijuana or obtains it from a primary caregiver or a medical marijuana center, the patient must first obtain, from a Colorado-licensed physician, a diagnosis of suffering from one of the enumerated debilitating or disabling medical conditions: [11]

- Cancer
- Glaucoma
- Positive status for human immunodeficiency virus or AIDS
- Cachexia
- Severe pain
- Severe nausea
- Seizures
- Persistent muscle spasms
- Post-traumatic stress disorder[12]

The physician must also find that the patient "might benefit from the medical use of marijuana."[13]

The patient may then apply to CDPHE for a medical marijuana registry identification card, which, in turn, is presented to law enforcement as needed, the patient's primary caregiver and the medical marijuana center from which the patient obtains medical marijuana.

Medical marijuana is now available in a variety of forms. The dried buds and leaves of the cannabis plant may be smoked through a variety of paraphernalia, including joints, pipes or bongs. The cannabinoid crystals may also be harvested and dried to form hash, which can also be smoked. Cannabinoid oils can be extracted from the cannabis plant and used to create tinctures, ointments and concentrates, which can, in turn be infused into an infinite number of edible products. These are but a few examples.

[11] Colo. Const. Art. XVIII, §§ 14 (1)(a)(I and II) and § 25-1.5-106(2)(a.7), C.R.S.
[12] Both physicians and licensed mental health providers can diagnose post-traumatic stress disorder, but only physicians can recommend medical marijuana for its treatment.
[13] Colo. Const. Art. XVIII, § 14(2)(a)(II).

While there is no way to measure the total amount of medical marijuana consumed in the state, in 2017, Colorado's licensed medical marijuana establishments sold to patients approximately 172,994 pounds of marijuana flower,[14] approximately 1.9 million units of marijuana-infused edible products[15] and 210,823 units of marijuana-infused non-edible products.[16]

To date, all but four states have legalized medical marijuana in some manner, and nine have legalized the recreational use of marijuana.[17]

Although both medical and retail marijuana are widely available in Colorado, all forms of marijuana remain illegal under federal law.

[14] *MED 2017 Annual Update*, Colorado Department of Revenue, Marijuana Enforcement Division (May 17, 2018), p. 10.
[15] *MED 2017 Annual Update*, Colorado Department of Revenue, Marijuana Enforcement Division (May 17, 2018), p. 11.
[16] *MED 2017 Annual Update*, Colorado Department of Revenue, Marijuana Enforcement Division (May 17, 2018), p. 11.
[17] National Conference of State Legislatures. *Marijuana Deep Dive*. Retrieved May 23, 2018, from www.ncsl.org/bookstore/state-legislatures-magazine/marijuana-deep-dive.aspx

Legal Framework

History of Regulation

On November 7, 2000, the voters of Colorado passed Amendment 20 to the state's constitution, effectively decriminalizing the medical use of the drug. Amendment 20 became effective on December 28, 2000.

The provisions of Amendment 20 create an affirmative defense for any patient, or the patient's primary caregiver, whose physician has diagnosed the patient as having a debilitating medical condition, and whose physician has advised the patient that the patient might benefit from the use of medical marijuana.[18]

Amendment 20 also provides for the creation of a registry of medical marijuana patients, including requirements for inclusion on the registry and the issuance of registry identification cards.[19]

Amendment 20 generally limits possession of medical marijuana to no more than two ounces of marijuana in a useable form and no more than six plants. However, the patient or the patient's primary caregiver may raise as an affirmative defense that more than these general limitations are medically necessary to address the patient's condition,[20] when so recommended by a physician.

Patients must be at least 18 years old. An individual under 18 may use medical marijuana only when two physicians recommend its use and the patient's parents consent.[21]

No health insurance carrier, neither public nor private, is required to provide reimbursements for medical marijuana,[22] and no employer is required to accommodate the use of medical marijuana in the workplace.[23]

Amendment 20 directs the Governor to designate a "state health agency" to implement the constitutional provision,[24] which the Governor did in Executive Order D 001 01, designating the Colorado Department of Public Health and Environment (CDPHE) as the state health agency. The General Assembly, in passing House Bill 01-1371, granted CDPHE broad rule-making authority to promulgate the registry application forms, the processes for issuing medical marijuana registry cards and the manner in which CDPHE could consider adding to the list of debilitating medical conditions outlined in Amendment 20.

[18] Colo. Const. Art. XVIII, § 14(2)(a).
[19] Colo. Const. Art. XVIII, §§ 14(2)(b) and (3).
[20] Colo. Const. Art. XVIII, § 14(4).
[21] Colo. Const. Art. XVIII, § 14(6).
[22] Colo. Const. Art. XVIII, § 14(10)(a).
[23] Colo. Const. Art. XVIII, § 14(10)(b).
[24] Colo. Const. Art. XVIII, § 14(7).

In the years that followed, local governments began licensing medical marijuana dispensaries.

On October 19, 2009, the United States Department of Justice issued what has come to be known as the "Ogden Memo," which, while recognizing the plenary authority of the various United States Attorneys, directed they,

> should not focus federal resources in [their] states on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.[25]

Thus, the 2010 legislative session began within the context of Colorado's local governments having created a patchwork of regulations and the federal government having indicated that it might not enforce federal law with fervor.

The two major marijuana-related pieces of legislation passed in 2010 were Senate Bill 109 and House Bill 1284 (HB 1284). The first defined a "bona fide physician-patient relationship," more clearly delineating the qualifications of physicians who recommend medical marijuana to their patients, outlining the process physicians must follow when recommending medical marijuana and prohibiting physicians from holding an economic interest in an enterprise that provides or distributes medical marijuana.

House Bill 1284 created the Colorado Medical Marijuana Code (Medical Code). Among other things, the bill created the framework for the licensing of medical marijuana centers, their cultivation operations, medical marijuana-infused products (MMIPs) manufacturers and the individuals who work in such facilities.

House Bill 11-1043, among other things, specified that a physician who recommends medical marijuana must hold an active, unrestricted medical license and required primary caregivers who cultivate marijuana for their patients to register the location of their cultivations with the Department of Revenue's Marijuana Enforcement Division (MED). The bill further directed MED to verify the location of such a cultivation to a local government or law enforcement agency only upon receiving an address-specific request. Finally, the bill directed CDPHE to waive the medical marijuana registry application fee for applicants whose income is 185 percent or less of the federal poverty line.

In 2014, the General Assembly passed two pieces of legislation related to the CDPHE's medical marijuana program. First, Senate Bill 155 created the Medical Marijuana Health Research Grant Program and the Scientific Advisory Council. Next, House Bill 1396 prohibited a primary caregiver from providing services to anyone who does not hold a registry identification card and who does not designate that caregiver as such on the medical marijuana registry.

[25] U.S. Department of Justice. *Memorandum for Selected United States Attorneys, from David W. Ogden, Deputy Attorney General, regarding Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana*, October 19, 2009. Retrieved July 24, 2018, from www.justice.gov/archives/opa/blog/memorandum-selected-united-state-attorneys-investigations-and-prosecutions-states

Senate Bill 15-014 addressed several medical marijuana issues, including creating different types of caregivers: parents of minor patients, advising caregivers, cultivating caregivers and transporting caregivers. The bill directed CDPHE to convene a working group to explore laboratory testing options for medical marijuana that is grown outside of MED's licensed regime. Patients growing more than six plants for their own use were encouraged to register with MED and patients were prohibited from growing more than 99 plants. The bill also limited the number of plants caregivers can grow and where. Finally, the bill, along with Senate Bill 15-115, scheduled the program for a sunset review.

Also in 2015, House Bill 1283 directed CDPHE to establish a marijuana laboratory testing reference library, to be accessible to testing laboratories licensed by MED. The bill also made CDPHE responsible for proficiency testing and remediation problems by those licensees.

House Bill 16-1373 expanded the use of medical marijuana by students to include school sponsored events.

Senate Bill 17-017 authorized the use of medical marijuana for post-traumatic stress disorder and declared it to be a disabling medical condition (as compared to Amendment 20's debilitating medical conditions).

In an attempt to prevent the diversion of marijuana to the black market, House Bill 17-1220 generally limited to 12 the total number of marijuana plants (medical and recreational combined) that can be cultivated on a residential property, and it created criminal penalties for those who violate that limitation.

Federal Laws and Guidance

The federal Controlled Substances Act classifies marijuana and the cannabinoid tetrahydrocannabinol (THC) in Schedule I, [26] which means that they have a high potential for abuse, they have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of them under medical supervision.[27] As such, both substances are illegal under federal law.

Their legal status means that possession of any amount of marijuana is punishable by up to a year in prison and a fine of $1,000 for a first offense, and a second offense carries a mandatory penalty of between 15 days and two years in prison and a $2,500 fine. Subsequent offenses can carry a prison term of between 90 days and three years, plus a $5,000 fine.[28]

[26] 21 U.S.C. §§ 812(c)(c)(10) and (17).
[27] 21 U.S.C. § 812(b)(1).
[28] LegalMatch. *Federal Laws for Marijuana Possession and Distribution.* Retrieved May 9, 2018, from www.legalmatch.com/law-library/article/federal-marijuana-laws.html

The penalties for selling or cultivating marijuana depend on the amount at issue:[29]

- Less than 50 plants or kilograms = up to five years in prison and a fine of $250,000;
- 50 to 99 plants or kilograms = up to 20 years in prison and a fine of $1 million;
- 100 to 999 plants or kilograms = between 5 and 40 years in prison and a fine of $500,000; and
- More than 1,000 plants or kilograms = between 10 years and life in prison and a fine of $1 million.

In addition to the relatively simple issues of possession, cultivation and sale of marijuana, the plant's status under federal law raises other, more complicated legal matters. These include, but are not limited to, banking and the utilization of the Federal Reserve System, money laundering, air emissions, water emissions, the use of pesticides and the payment of taxes (including deductible and allowable expenses).

The United States Department of Justice (DOJ), recognizing the fact that nearly half the states had either decriminalized or legalized medical marijuana, issued a memorandum in 2013 to all United States Attorneys providing guidance regarding marijuana enforcement. That memorandum, often referred to as the "Cole Memo," delineated the DOJ's enforcement priorities as preventing:[30]

- The distribution of marijuana to minors;
- Revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- The diversion of marijuana from states where it is legal under state law in some form to other states;
- State-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Violence and the use of firearms in the cultivation and distribution of marijuana;
- Drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Growing marijuana on public land and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Marijuana possession or use on federal property.

While the Cole Memo's guidance reinforces the DOJ's position that United States Attorneys and federal law enforcement should continue to focus on the enumerated priorities, it also clarified the DOJ's expectation,

> that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory

[29] LegalMatch. *Federal Laws for Marijuana Possession and Distribution.* Retrieved May 9, 2018, from www.legalmatch.com/law-library/article/federal-marijuana-laws.html

[30] U.S. Department of Justice. *Memorandum for all United States Attorneys, from James M. Cole, Deputy Attorney General, regarding Guidance Regarding Marijuana Enforcement,* August 29, 2013, pp. 1-2. Retrieved May 9, 2018, from www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf

> and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests.[31]

In such circumstances,

> enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity.[32]

Taken together, these provisions were generally interpreted as meaning that so long as state law created a robust regulatory environment that was strongly enforced, the federal government would not interfere except in those individual cases where the DOJ's enforcement priorities were at risk.

However, on January 4, 2018, the DOJ rescinded all previous guidance related to its enforcement of the nation's marijuana laws. In doing so, the DOJ reiterated its general principles that,

> require federal prosecutors deciding which cases to prosecute to weigh all relevant considerations, including federal law enforcement priorities set by the Attorney General, the seriousness of the crime, the deterrent effect of criminal prosecution, and the cumulative impact of particular crimes on the community.[33]

Medical Marijuana under Colorado Law

Medical marijuana is regulated by the state's constitution; by the Medical Marijuana Code (Medical Code), which is administered by the Colorado Department of Revenue's Marijuana Enforcement Division (MED), and by the medical marijuana program administered by the Colorado Department of Public Health and Environment (CDPHE). Only the medical marijuana program at CDPHE is the subject of this sunset review. The Medical Code and the Retail Marijuana Code are reviewed in a separate sunset report.

Although the state's constitution does not define medical marijuana, it defines medical use as:

> the acquisition, possession, production, use, or transportation of marijuana or paraphernalia related to the administration of such marijuana to address

[31] U.S. Department of Justice. *Memorandum for all United States Attorneys, from James M. Cole, Deputy Attorney General, regarding Guidance Regarding Marijuana Enforcement,* August 29, 2013, p. 2. Retrieved May 9, 2018, from www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf

[32] U.S. Department of Justice. *Memorandum for all United States Attorneys, from James M. Cole, Deputy Attorney General, regarding Guidance Regarding Marijuana Enforcement,* August 29, 2013, p. 3. Retrieved May 9, 2018, from www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf

[33] U.S. Department of Justice. *Memorandum for all United States Attorneys, from Jefferson B. Sessions, Attorney General, regarding Marijuana Enforcement*. January 4, 2018. Retrieved June 4, 2018, from www.justice.gov/opa/press-release/file/1022196/download

> the symptoms or effects of a patient's debilitating medical condition, which may be authorized only after a diagnosis of the patient's debilitating medical condition by a physician or physicians. . .[34]

For the purposes of medical marijuana, a patient is a person who has a debilitating or disabling medical condition.[35]

Cancer, glaucoma, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, cachexia, severe pain, severe nausea, seizures and persistent muscle spasms constitute debilitating medical conditions under the constitution.[36]

To add to the list of debilitating medical conditions, a physician or patient must submit a petition to CDPHE, the Executive Director of which must review the information in the petition and[37]

> 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 . . .

While no additional debilitating medical conditions have been defined by CDPHE, the General Assembly has defined post-traumatic stress disorder as a disabling medical condition when diagnosed by a licensed mental health provider or a physician.[38]

In short, state law creates an affirmative defense to the state's criminal laws relating to the use of marijuana where the patient:[39]

- Was diagnosed by a physician as having a debilitating or disabling medical condition;
- Was advised by his or her physician that the patient might benefit from the medical use of marijuana; and
- Was in possession of amounts of marijuana only as permitted by the state's constitution.

A physician who recommends marijuana to a patient with a debilitating or disabling medical condition must hold a license, in good standing, to practice medicine[40] and have a bona-fide physician-patient relationship with the patient.[41] If the physician finds that the patient "may benefit from the use of medical marijuana," the physician must certify

[34] Colo. Const. Art. XVIII, § 14(1)(b).
[35] Colo. Const. Art. XVIII, § 14(1)(d) and § 25-1.5-106(2)(d.3), C.R.S.
[36] Colo. Const. Art. XVIII, §§ 14(1)(a)(I and II).
[37] Colo. Const. Art. XVIII, § 14(1)(a)(III), and 5 CCR § 1006-2(6)(D), Medical Use of Marijuana Rules.
[38] § 25-1.5-106(2)(a.7), C.R.S.
[39] Colo. Const. Art. XVIII, § 14(2)(a) and § 25-1.5-106(2.5), C.R.S.
[40] § 25-1.5-106(5)(a), C.R.S.
[41] § 25-1.5-106(5)(b), C.R.S.

as much to CDPHE.[42] The physician must also specify the medical condition and the cause or source of the condition.[43]

A bona fide physician-patient relationship exists when:[44]

- The physician and patient have a treatment or counseling relationship in which the physician has completed a full assessment of the patient's medical history, including reviewing previous diagnoses and current medical condition and conducting an appropriate physical examination;
- The physician has consulted with the patient regarding the patient's debilitating or disabling medical condition; and
- The physician is available to or offers to provide follow-up care and treatment.

A physician must also possess a valid and unrestricted controlled substances registration issued by the U.S. Drug Enforcement Administration.[45]

Physicians must maintain a record-keeping system for all medical marijuana patients and, pursuant to an investigation, must produce those records to the Colorado Medical Board after redacting any patient or primary caregiver identifying information.[46]

If CDPHE has reason to believe that a physician has violated any of these provisions, the state constitution's medical marijuana provisions or CDPHE's rules, CDPHE may refer the physician to the Colorado Medical Board for investigation.[47]

A physician must not:[48]

- Accept, solicit or offer any form of pecuniary remuneration from or to a primary caregiver, distributor or any other provider of medical marijuana;
- 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;
- Examine a patient for purposes of diagnosing a debilitating medical condition or disabling medical condition at a location where medical marijuana is sold or distributed; or
- Hold an economic interest in an enterprise that provides or distributes medical marijuana if the physician certifies the debilitating medical condition or disabling medical condition of a patient for participation in the program.

If CDPHE has reasonable cause to believe that a physician has violated any of these provisions, it must conduct a hearing to determine whether such a violation occurred.[49]

[42] § 25-1.5-106(5)(b), C.R.S.
[43] § 25-1.5-106(5)(b), C.R.S.
[44] § 25-1.5-106(2)(a.5), C.R.S.
[45] 5 CCR § 1006-2(8)(A)(1)(a)(iii), Medical Use of Marijuana Rules.
[46] § 25-1.5-106(5)(c), C.R.S., and 5 CCR § 1006-2(8)(3), Medical Use of Marijuana Rules.
[47] § 25-1.5-106(6)(a), C.R.S.
[48] § 25-1.5-106(5)(d), C.R.S., and 5 CCR § 1006-2(8)(4), Medical Use of Marijuana Rules.
[49] § 25-1.5-106(6)(b), C.R.S.

If either the Colorado Medical Board or CDPHE find a physician has violated the provisions within their respective jurisdictions, CDPHE must restrict the physician's authority to recommend the use of medical marijuana. Such restrictions may include suspension or revocation of a physician's privileges to recommend medical marijuana and are in addition to any sanction imposed by the Colorado Medical Board.[50]

No patient under the age of 18 can use medical marijuana unless:[51]

- Two physicians, one of whom must be part of the patient's primary care provider team, have diagnosed the patient as having a debilitating or disabling medical condition and one of whom has explained the possible risks and benefits of medical marijuana to the patient and the patient's parents;
- Each of the patient's parents consent;
- A parent serving as a primary caregiver completes and submits an application for a registry identification card and the written parental consent;
- CDPHE approves the application; and
- The primary caregiver controls the acquisition of the medical marijuana, as well as the dosage and frequency of its use.

A medical marijuana patient may possess no more than two ounces of a useable form of marijuana and no more than six marijuana plants, with three or fewer being mature, flowering plants that are producing a useable form of marijuana. A patient may possess more than this if he or she can demonstrate that a greater amount is medically necessary to treat the patient's debilitating or disabling medical condition.[52]

CDPHE is required to promulgate rules establishing and maintaining a confidential registry of patients.[53] Such rules must include the conditions for issuance and renewal, and the form of the registry identification cards, including standards for ensuring that the patient has a bona fide physician-patient relationship with a physician.[54]

To register, a patient must:

- Reside in Colorado;[55]
- Provide a copy of a secure and verifiable identity document, such as a driver's license;[56]
- Provide original documentation stating that the patient has a debilitating or disabling medical condition; [57]

[50] § 25-1.5-106(6)(c), C.R.S.
[51] Colo. Const. Art. XVIII, § 14(6), § 25-1.5-106(2.5)(i), C.R.S., and 5 CCR § 1006-2(2)(B), Medical Use of Marijuana Rules.
[52] Colo. Const. Art. XVIII, § 14(4) and § 25-1.5-106(2.5)(g), C.R.S.
[53] Colo. Const. Art. XVIII, § 14(3) and § 25-1.5-106(3)(a)(I), C.R.S.
[54] § 25-1.5-106(3)(a)(V), C.R.S.
[55] Colo. Const. Art. XVIII, § 14(3)(b), and 5 CCR § 1006-2(2)(A), Medical Use of Marijuana Rules.
[56] 5 CCR 1006-2(2)(A)(6).
[57] Colo. Const. Art. XVIII, § 14(3)(b)(I) and 5 CCR § 1006-2(2)(A)(3), Medical Use of Marijuana Rules.

- Provide the patient's name, address, date of birth and social security number; and[58]
- Provide the name, address and telephone number of the patient's physician.[59]

Additionally, the patient must indicate whether the patient will utilize a primary caregiver or a medical marijuana center.[60] If a caregiver will be utilized, the patient must provide the name and address of the caregiver; the patient's record will reflect this and the caregiver's name will appear on the registry identification card.[61] If a medical marijuana center will be utilized, the patient's record will reflect this but specific medical marijuana center information will not be reflected on the registry identification card.[62]

CDPHE must approve or deny a registration application within 30 days of receiving a complete application. The registry identification card must state:[63]

- The patient's name, address, date of birth and social security number;
- That the patient has been certified as having a debilitating or disabling medical condition;
- The date of issuance and expiration of the registry identification card; and
- The name and address of the patient's primary caregiver, if one is designated at the time of application.

CDPHE may reject an application as incomplete if the information in the application is illegible or missing or if the physician is not eligible to recommend medical marijuana. A patient has 60 days to make any necessary corrections.[64]

CDPHE may deny an application if:[65]

- The physician recommendation is falsified;
- Any information in the application is falsified;
- The identification card presented with the application is not the patient's;
- The applicant is not a Colorado resident; or
- CDPHE has twice rejected the patient's application, and the third application is incomplete.

If CDPHE denies an application, the patient may not reapply for six months.[66]

Although a patient may register as such with CDPHE, only those who register and are in possession of their registry cards at all times that they are in possession of medical

[58] Colo. Const. Art. XVIII, § 14(3)(b)(II) and 5 CCR § 1006-2(2)(A)(1), Medical Use of Marijuana Rules.
[59] Colo. Const. Art. XVIII, § 14(3)(b)(III) and 5 CCR § 1006-2(2)(A)(5), Medical Use of Marijuana Rules.
[60] 5 CCR § 1006-2(2)(A)(2), Medical Use of Marijuana Rules.
[61] Colo. Const. Art. XVIII, § 14(3)(b)(IV) and 5 CCR § 1006-2(2)(A)(2)(a), Medical Use of Marijuana Rules
[62] 5 CCR § 1006-2(2)(A)(2)(b), Medical Use of Marijuana Rules.
[63] Colo. Const. Art. XVIII, § 14(3)(c).
[64] 5 CCR § 1006-2(2)(E), Medical Use of Marijuana Rules.
[65] 5 CCR § 1006-2(2)(F), Medical Use of Marijuana Rules.
[66] 5 CCR § 1006-2(2)(F), Medical Use of Marijuana Rules.

marijuana are considered to be in compliance with the state's constitution and program statutes and rules. However, if CDPHE has not denied or issued a registry card more than 35 days after the patient applied, compliance with the constitution and program statutes and rules may be demonstrated by possession of a copy of the application along with proof of the date of submission. [67]

Patient and caregiver registry cards are valid for one year.[68] Patient registry cards may be denied or revoked for one year if the patient's physician, the patient or the primary caregiver violates any provision of the constitution pertaining to medical marijuana or program statutes or rules.[69]

When a patient applies for a registry identification card, he or she must indicate whether the patient intends to:[70]

- Cultivate his or her own medical marijuana;
- Both cultivate his or her own medical marijuana and obtain it from either a caregiver or a licensed medical marijuana center; or
- Obtain his or her medical marijuana from either a caregiver or a licensed medical marijuana center.

The confidentiality of the information in the registry is enshrined in the constitution:[71]

> No person shall be permitted to gain access to any information about patients in the . . . confidential registry, or any information otherwise maintained by [CDPHE] about physicians and primary caregivers, except for authorized employees of [CDPHE] in the course of their official duties and authorized employees of state or 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 or its functional equivalent . . .

Unless expressly authorized by local law, no patient may possess or cultivate on a residential property, regardless of the number of people residing at the property, more than 12 marijuana plants.[72]

Patients cultivating more than six medical marijuana plants for their own use are "encouraged" to register, with MED, the location of the cultivation and the total number of plants that the patient is authorized to cultivate.[73]

A patient may possess or cultivate up to 24 marijuana plants on a residential property, regardless of the number of people residing on the property, if the patient:[74]

[67] Colo. Const. Art. XVIII, § 14(3)(d) and § 25-1.5-106(9)(a), C.R.S.
[68] § 25-1.5-106(9)(c), C.R.S., and 5 CCR § 1006-2(2)(B), Medical Use of Marijuana Rules.
[69] § 25-1.5-106(9)(b), C.R.S., and 5 CCR § 1006-2(2)(G), Medical Use of Marijuana Rules.
[70] § 25-1.5-106(8)(f), C.R.S.
[71] Colo. Const. Art. XVIII, § 14(3)(a).
[72] Colo. Const. Art. XVIII, § 14(4) and § 25-1.5-106(8.5)(a.5)(I), C.R.S.
[73] § 25-1.5-106(8.5), C.R.S.
[74] § 25-1.5-106(8.5)(a.5)(I), C.R.S.

- Lives in a local jurisdiction that does not limit the number of marijuana plants that may be grown in or on a residential property,
- Registers the cultivation with MED, and
- Provides notice to the local jurisdiction of the residential cultivation if required by the local jurisdiction.

A patient who grows more than 24 plants must locate the cultivation at a property other than a residential property,[75] but in no case may a patient cultivate more than 99 plants.[76] Only a medical marijuana business licensed by MED under the Medical Code may cultivate more than 99 plants.[77]

The information reported to MED for the purpose of registering a medical marijuana cultivation must not be provided to the public and is confidential, and it may only be provided to a local jurisdiction or law enforcement when MED receives a request for verification.[78]

A patient may opt to obtain medical marijuana from a primary caregiver, who is a person, other than the patient or the patient's physician, who is at least 18 years old and has "significant responsibility for managing the well-being" of the patient.[79]

A "significant responsibility for managing the well-being of a patient" means that[80]

> 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."

Primary caregivers are prohibited from delegating their authority to provide medical marijuana to a patient, and they are prohibited from engaging others to assist in providing medical marijuana to a patient.[81] While a primary caregiver may charge for caregiver services, when charging for medical marijuana, he or she cannot charge more than the cost of cultivating or purchasing the medical marijuana.[82]

A caregiver may have one or more of the following relationships with his or her patients:[83]

- A parent of a patient under age 18, and anyone who assists that parent with caregiver responsibilities;

[75] § 25-1.5-106(8.5)(a.5)(II), C.R.S.
[76] § 25-1.5-106(8.5)(b), C.R.S.
[77] § 25-1.5-106(8.5)(b), C.R.S.
[78] § 25-1.5-106(8.5)(c), C.R.S.
[79] Colo. Const. Art. XVIII, § 14(1)(f), § 25-1.5-106(1)(d.5), C.R.S., and 5 CCR § 1006-2-1(1)(C)(5), Medical Use of Marijuana Rules.
[80] § 25-1.5-106(2)(e.5), C.R.S., and 5 CCR § 1006-2(1)(C)(6), Medical Use of Marijuana Rules.
[81] § 25-1.5-106(7)(a), C.R.S.
[82] § 25.1.5-106(8)(d), C.R.S.
[83] 5 CCR § 1006-2(2)(C)(5), Medical Use of Marijuana Rules.

- An advising caregiver who advises a patient on which medical marijuana products to use and how to dose them, and who does not possess, provide, cultivate or transport medical marijuana on behalf of the patient;
- A transporting caregiver who purchases and transports medical marijuana to a patient who is homebound; and
- A cultivating caregiver who grows marijuana for the patient.

Unless expressly authorized by CDPHE, a caregiver may serve as such for no more than five patients at any given time,[84] and a patient must have only one caregiver at any given time.[85] A patient who designates another as his or her caregiver cannot also serve as a caregiver to another patient.[86]

In acting upon an application to waive the five-patient maximum, CDPHE considers:[87]

- Information submitted by the patient and caregiver;
- Any county-wide prohibitions on medical marijuana centers;
- The proximity of medical marijuana centers to the patient;
- Whether granting the waiver would either benefit or adversely affect the health, safety or welfare of the patient; and
- What services beyond providing medical marijuana the patient needs from the caregiver.

CDPHE is required to maintain a secure and confidential registry of available caregivers for patients who are unable to secure the services of a caregiver.[88] Caregivers who are so registered may waive confidentiality to allow the release of their contact information to physicians and registered patients only.[89]

Any primary caregiver who cultivates or transports medical marijuana for his or her patients is required to register with MED.[90] When registering a cultivation, the primary caregiver must provide the location of the cultivation, the registry identification number of each patient for whom medical marijuana is grown and any extended plant count numbers.[91]

A primary caregiver who transports medical marijuana to homebound patients must provide, when registering, the registry number of each patient, the total number of plants and ounces that the caregiver is authorized to transport and the location of each patient's medical marijuana center or cultivating primary caregiver, as applicable.[92]

[84] § 25-1.5-106(8)(a)(I), C.R.S.
[85] § 25-1.5-106(8)(b), C.R.S.
[86] 5 CCR § 1006-2(9)(A), Medical Use of Marijuana Rules.
[87] 5 CCR § 1006-2(10)(D), Medical Use of Marijuana Rules.
[88] § 25-1.5-106(8)(e)(I), C.R.S.
[89] § 25-1.5-106(8)(e)(II), C.R.S.
[90] § 25-1.5-106(7)(e)(I)(A), C.R.S.
[91] § 25-1.5-106(7)(e)(I)(B), C.R.S.
[92] § 25-1.5-106(7)(e)(I)(C), C.R.S.

A caregiver must not grow, sell or process marijuana for anyone unless the person is a patient with a valid registry identification card and the caregiver is currently identified on the medical marijuana registry as the patient's caregiver.[93]

In general, a caregiver may possess, cultivate or transport no more than 36 marijuana plants, unless the caregiver has one or more patients with extended plant counts.[94]

Unless expressly authorized by local law, no caregiver may possess or cultivate on a residential property, regardless of the number of people residing at the property, more than 12 marijuana plants.[95]

However, a caregiver may possess or cultivate up to 24 marijuana plants on a residential property, regardless of the number of people residing on the property, if the caregiver:[96]

- Lives in a local jurisdiction that does not limit the number of marijuana plants that may be grown in or on a residential property;
- Registers the cultivation with MED; and
- Provides notice to the local jurisdiction of the residential cultivation if required by the local jurisdiction.

A caregiver who grows more than 24 plants must locate the cultivation at a property other than a residential property,[97] and a caregiver who cultivates more than 36 plants must register with MED, by providing information pertaining to:[98]

- The location of the cultivation;
- The patient registration identification for each patient; and
- Any expended plant counts for those patients.

In no case may a caregiver cultivate more than 99 plants. Only a medical marijuana business licensed by MED under the Medical Code may cultivate more than 99 plants.[99]

A patient or primary caregiver must not:[100]

- Use medical marijuana in a way that endangers the health and well-being of a person;
- Use medical marijuana in plain view of or in a place open to the general public;
- Undertake any task while under the influence of medical marijuana, when doing so would constitute negligence or professional malpractice;

[93] § 25-1.5-106(8)(g), C.R.S.
[94] § 25-1.5-106(8.6)(a)(I), C.R.S.
[95] § 25-1.5-106(8.6)(a)(I.5), C.R.S.
[96] § 25-1.5-106(8.6)(a)(I.5), C.R.S.
[97] § 25-1.5-106(8.6)(a)(I.6), C.R.S.
[98] § 25-1.5-106(8.6)(a)(II), C.R.S.
[99] § 25-1.5-106(8.6)(b), C.R.S.
[100] Colo. Const. Art. XVIII, § 14(5), § 25-1.5-106(12)(b), C.R.S., and 5 CCR §§ 1006-2(9)(J) and 1006-2(12)(C), Medical Use of Marijuana Rules.

- Possess medical marijuana or otherwise engage in the use of medical marijuana in or on the grounds of a school, in a school bus, or at a school-sponsored event unless the use or possession occurs pursuant to the school's policy regarding possession and administration of prescription medications;
- Use medical marijuana while in a correctional or community corrections facility, subject to a sentence to incarceration or in a vehicle, aircraft or motorboat;
- Operate, navigate or be in actual physical control of any vehicle, aircraft or motorboat while under the influence of medical marijuana; or
- Use medical marijuana if the person does not have a debilitating or disabling medical condition.

The statute explicitly prohibits any person from establishing a business that allows patients to congregate and smoke, or otherwise consume, medical marijuana.[101]

CDPHE must develop and maintain a marijuana laboratory testing reference library, which must contain a library of methodologies for marijuana testing in the areas of potency, homogeneity, contaminants and solvents.[102] The library may include standard sample attainment procedures and standards related to sample preparation for laboratory analysis.[103]

Finally, CDPHE is responsible for proficiency testing and remediating problems with laboratories licensed by MED under the Medical and Retail Marijuana Codes.[104]

[101] § 25-1.5-106(12)(c), C.R.S.
[102] §§ 25-1.5-106(3.5)(a and b), C.R.S.
[103] § 25-1.5-106(c), C.R.S.
[104] § 25-1.5-106(3.8), C.R.S.

Program Description and Administration

Amendment 20 to the state's constitution requires the Governor to designate a "state health agency" to establish and maintain a medical marijuana patient registry and to promulgate rules to administer that program. By way of Executive Order D 001 01, the Governor designated the Colorado Department of Public Health and Environment (CDPHE) as that agency. As a matter of practice, CDPHE administers the program and the Colorado Board of Health (Board of Health) promulgates the envisioned rules.

As such, CDPHE performs many tasks associated with medical marijuana, including:

- Administering the medical marijuana patient registry, including establishing standards for creating a bona fide physician-patient relationship;
- Assisting the Colorado Department of Revenue's Marijuana Enforcement Division (MED) in the certification of MED-licensed marijuana testing facilities and conducting proficiency testing of such facilities;
- Maintaining a marijuana laboratory testing reference library; and
- Establishing a process to add to the list of debilitating medical conditions already enumerated in the state's constitution.

While CDPHE engages in other marijuana-related activities, only those enumerated above fall within the scope of this sunset review.

Table 1 illustrates, for the fiscal years indicated, the number of full-time equivalent (FTE) employees devoted to the medical marijuana patient registry, and CDPHE's expenditures related to the registry.

Table 1
Medical Marijuana Registry Fiscal Information

Fiscal Year	FTE	Expenditures
12-13	33.0	$2,555,394
13-14	32.0	$2,517,624
14-15	25.9	$2,420,195
15-16	24.3	$2,300,095
16-17	18.6	$2,032,166

The steady decline in program staff and expenditures can be attributed to increased efficiencies gained through process improvements and, most recently, the launch of an online registration system which substantially reduced costs associated with postage, printing, supplies and FTE needed to administer the program.

The 14.0 FTE dedicated to the registry at the time of this writing consist of:

- 1.0 FTE Program Management II: Program Manager. This position manages the medical marijuana registry and day to day communications, operations and budgeting.
- 1.0 FTE Administrator V: Program Support Manager. This position oversees customer service, system administration and communications.
- 1.0 FTE Administrator IV: System Administrator. This position is responsible for developing and maintaining the online registration system, and coordinates with the system vendor.
- 1.0 FTE Program Assistant II: Customer Service Specialist. This position oversees the customer service team.
- 1.0 FTE Marketing and Communications Specialist III. This position is responsible for registry-related communications and website administration.
- 1.0 FTE Technician V: Operations Supervisor. This position oversees the evaluation and processing of registry applications.
- 7.0 Technician II. Four of these employees provide customer support via phone and email, as well as process registry applications. Three of these employees evaluate and process registry applications.
- 1.0 FTE Administrative Assistant III. This position processes payments, performs statistical analysis, serves as a back up to the System Administrator and performs other administrative duties.

The medical marijuana registry has three primary components: physicians, patients and caregivers. However, the first step in the lawful use of medical marijuana is being diagnosed with a debilitating or disabling medical condition.

Debilitating Medical Conditions

The state constitution defines a debilitating medical condition as:[105]

- Cancer, glaucoma, positive status for human immunodeficiency virus (HIV), or acquired immune deficiency syndrome (AIDS), or treatment for such conditions;
- A chronic or debilitating disease or medical condition, 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 reasonably may 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; or
- Any other medical condition, or treatment for such condition, approved by CDPHE, pursuant to its rule making authority or its approval of any petition submitted by a patient or physician.

[105] Colo. Const. Arv. XVIII, § 14(1)(a).

CDPHE is required by statute to promulgate rules addressing the process for adding to this list of debilitating medical conditions.[106] Those rules require physicians and patients seeking to add to the list to submit a petition to CDPHE, the Executive Director of which must then review the petition and submitted information and must,

> conduct a search of the medical literature for peer-reviewed published literature of randomized controlled trial 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.[107]

CDPHE must deny any such petition within 180 days of receipt of the petition if:[108]

- None of the required studies exist;
- The required studies exist but show harm, other than harm associated with smoking, and there are alternative, conventional treatments available; or
- The petition seeks the addition of an underlying condition for which the associated symptoms are already debilitating medical conditions.

If none of these conditions are present, CDPHE must petition the Board of Health to add the requested condition to the list of debilitating medical conditions.[109]

In the life of the program, CDPHE has received a total of 10 such petitions addressing 15 distinct conditions:

- Asthma (two petitions)
- Atherosclerosis
- Bi-polar disease
- Clinical depression
- Crohn's disease
- Diabetes mellitus, types 1 and 2
- Diabetic retinopathy
- Hepatitis C
- Hypertension
- Methacillin-resistant staphylococcus aureus
- Opioid dependence
- Post-traumatic stress disorder (PTSD)(four petitions)
- Rheumatoid arthritis (two petitions)
- Severe anxiety
- Tourette's syndrome

One petition submitted in 2010 requested the addition of 10 conditions.

[106] § 25-1.5-106(3)(a)(VII), C.R.S.
[107] 5 CCR § 1006-2(6)(D)(1), Medical Use of Marijuana Rules.
[108] 5 CCR § 1006-2(6)(D)(2), Medical Use of Marijuana Rules.
[109] 5 CCR § 1006-2(6)(D)(3), Medical Use of Marijuana Rules.

In all but two instances, CDPHE denied the petition and did not forward the petition to the Board of Health for rulemaking. However, CDPHE did forward the petitions for Tourette's syndrome (2010) and PTSD (2015) to the Board of Health. A review of Board of Health minutes from these rule making hearings indicates that the conditions were not added to the list of debilitating medical conditions because the Board of Health found that there was a lack of scientific evidence to support their addition. The Board of Health was unanimous in making this finding regarding Tourette's syndrome, but divided—six to two—regarding PTSD.

Medical Marijuana Registry: Physicians

To obtain a medical marijuana registry identification card, an individual must be a Colorado resident and suffer from at least one of the following, as diagnosed by a Colorado-licensed physician:

- Cancer or treatment for cancer;
- Glaucoma or treatment for glaucoma;
- Positive status for HIV or AIDS, or treatment for such conditions;
- Cachexia;
- Severe pain;
- Severe nausea;
- Seizures, including those characteristic of epilepsy;
- Persistent muscle spasms, including those characteristic of multiple sclerosis; or
- PTSD.[110]

Statute requires that a bona fide physician-patient relationship exist before a physician may recommend medical marijuana to a patient. As a result, the first step in obtaining such a recommendation, and thus a medical marijuana registry identification card, is for the patient to visit a physician for an examination. If the physician determines that medical marijuana is likely to help the patient, the physician will write a recommendation that identifies the debilitating or disabling medical condition that qualifies the patient for the recommendation, as well as the number of medical marijuana plants that are medically necessary for the patient.

[110] Post-traumatic stress disorder can also be diagnosed by a licensed mental health provider, but only a physician can recommend medical marijuana.

Table 2 illustrates the number of patients relative to the number of medical marijuana plants recommended by physicians.

Table 2
Patient Plant Count Recommendations as of December Each Year

Recommended Plant Count	Number of Patients in 2016	Number of Patients in 2017	Difference from Prior Year
1 to 6	75,482	77,601	+2,119 (+2.8%)
7 to 10	52	55	+3 (+5.8%)
11 to 25	11,580	10,964	-616 (-5.3%)
26 to 50	3,817	2,743	-1,074 (-28.1%)
51 to 75	877	1,778	+901 (+102.7%)
76 to 100	2,769	231	-2,538 (-91.7%)
Over 100	0	0	No Change

CDPHE did not track the data provided in Table 2 until 2016, therefore data for the years prior to this time are not available. Regardless, it is clear that in one year, the number of patients with recommendations for between 76 and 100 plants plummeted 91.7 percent, while the number of patients with plant counts of between one and six increased 2.8 percent.

Some attribute this to the launch of CDPHE's online system in January 2017. That system more closely ties physicians to their medical marijuana patients, along with the recommended plant counts for those patients.

All medical marijuana physician recommendations must now be submitted by the recommending physician via CDPHE's online system. To create an online account, a physician must submit information pertaining to:

- Demographic information,
- Copy of a valid Colorado driver's license or identification card,
- National Provider Identification number,
- Colorado physician license number,
- Copy of a valid Colorado physician license,
- U.S. Drug Enforcement Administration (DEA) registration number,
- Copy of a valid DEA registration certificate with a Colorado address, and
- Signed confidentiality agreement attesting to the fact that the applicant is the one in control of the confidential and secure online account.

Once this information is verified, CDPHE sends the physician a user name and password so that the physician may begin recommending medical marijuana to his or her patients and directly uploading the recommendations into the medical marijuana registry.

As of June 2018, approximately 390 physicians had created online accounts.

Since CDPHE launched its online system, three physicians have had their access to that system restricted: two in 2017 and one as of July 2018. All were due to the Colorado Medical Board having taken action against their medical licenses.

Medical Marijuana Registry: Patients

Once a patient has obtained a recommendation for medical marijuana, the patient must apply to the medical marijuana registry to obtain a medical marijuana identification card, which will be presented to the patient's primary caregiver, if applicable, or to any medical marijuana center at which the patient seeks to purchase medical marijuana.

Although paper applications are still accepted, most are submitted via the online medical marijuana patient registration system. To register, the patient must provide demographic information, such as the patient's name, address, date of birth, social security number and driver's license number. The patient must also indicate how he or she intends to obtain his or her medical marijuana, whether by cultivating it himself or herself, obtaining it from a caregiver, obtaining it from a medical marijuana center or any combination thereof. If the patient intends to obtain medical marijuana from a caregiver, the patient must identify the caregiver services requested and provide the caregiver's registration identification number at the time of application. CDPHE then verifies this relationship with the caregiver. Patients can update their cultivation information at any time.

If the patient is a minor, the patient's parent must provide the aforementioned information.

The patient must attach his or her physician recommendation from a drop down menu and pay the required fee of $25. Alternatively, applicants whose income does not exceed 185 percent of the federal poverty line may seek a waiver from the $25-fee. Although historical data are not available, between October 2016 and August 2018, 275 waivers were granted.

CDPHE generally processes applications submitted online within a single business day. However, if an applicant submits information that is incorrect or invalid, the applicant receives a notification of such within one business day, along with instructions on how to submit corrected documents. Once approved, the patient's medical marijuana registry identification card is provided via the online system, and the patient can choose to print the card, or present it on a mobile device.

CDPHE also continues to accept paper applications, either by mail or on a walk-in basis. Table 3 illustrates, for the years indicated, the average processing time for such applications.

Table 3
Medical Marijuana Registry Application Processing Times

Calendar Year	Average Days to Process Mail Applications	Average Days to Process Online Applications
2015	21	Not Applicable
2016	15	Not Applicable
2017	29	1
2018	20	1

Because of the lag time in paper application processing, statute permits first-time applicants to use a copy of their application, along with a certified mail receipt indicating that their application had been submitted to CDPHE within the preceding 35 days, to identify themselves as medical marijuana patients to law enforcement, caregivers and medical marijuana centers prior to the issuance of a medical marijuana card. Patients registering via paper application will receive a paper registry identification card in the mail.

CDPHE currently receives and processes between 250 and 600 initial and renewal registration applications and requests each day. CDPHE staff also offers telephone support for the online system and general customer service inquiries, receiving approximately 200 calls each day.

Regardless of the manner in which patients register, all approved registrations are valid for one year from the date of issuance.

Table 4 illustrates, for the calendar years indicated, the total number of registered medical marijuana patients as of December of the years indicated.

Table 4
Medical Marijuana Registry, Active Patient Registrations as of December Each Year

Calendar Year	Active Medical Marijuana Patients	Change from Previous Year
2013	110,979	+2,453
2014	115,467	+4,488
2015	107,534	-7,933
2016	94,577	-12,957
2017	93,372	-1,205

Figures reported in Table 4 represent the number of patients holding registry identification cards as of December of the years indicated. The number of registered patients fluctuates from day to day because registry cards expire one year from the date of issuance. As a result, registry cards are being applied for, renewed and expire on a daily basis.

Although CDPHE staff cannot definitively explain the decline in medical marijuana registry identification cards beginning in 2015, the decline coincides with the legalization of recreational marijuana in the state.

Patients can also have their registrations denied or revoked. Table 5 illustrates, for the calendar years indicated, the number of denials and revocations.

Table 5
Medical Marijuana Registry, Denials and Revocations by Calendar Year

Calendar Year	Number of Denials	Number of Revocations	Combination Revocation & Denial
2015	2	0	0
2016	78	17	0
2017	12	2	2
Total	**92**	**19**	**2**

CDPHE did not track the data reported in Table 5 until 2015, thus there are no data available for prior to that time.

In 2017, two medical marijuana registry identification cards were both revoked and denied because the patients applied for renewal prior to the expiration of their current registry cards, but failed to satisfy the registration requirements. As a result, CDPHE revoked the current card and denied the renewal application. Common reasons for revocations may include the fact that the patient no longer lives in Colorado, the patient's physician revoked the recommendation for the patient or the patient was convicted of a drug-related offense.

When a registry card is denied or revoked, the patient has 30 days to appeal and request a hearing. In 2016, there were 18 such appeals, and there were four in 2017.

Medical Marijuana Registry: Primary Caregivers

A primary caregiver is a person who is age 18 or older and has significant responsibility for managing the well-being of a medical marijuana patient. There are several types of caregivers, each defined by the relationship with his or her patient(s): an advising caregiver, a transporting caregiver and a cultivating caregiver. Additionally, the parent of a minor patient must serve as the caregiver to that child.

Although caregivers may register with CDPHE via the medical marijuana registry, they have not, historically, been required to do so. However, as of January 2017, all caregivers cultivating more than 36 plants and transporting caregivers have been required to register with MED. CDPHE and MED developed a caregiver registration system that allows caregivers to register their demographic information with CDPHE to receive their caregiver identification card and register their cultivation location and any extended plant counts with MED.

This system was designed so that a caregiver can register in one place and CDPHE and MED view only certain fields within that registry, based on their respective roles. For example, MED does not access the caregiver's demographic information and CDPHE does not access the cultivation location or plant count information. No paper-based alternative is currently available for caregiver registrations.

Table 6 illustrates the total number of voluntarily registered caregivers as of the dates indicated, as well as the total number of registered cultivating caregivers.

Table 6
Caregiver Registration Information

Year	Total Number of Registered Caregivers	Total Number of Cultivating Caregivers
December 2016	2,531	Not Applicable
December 2017	2,507	518
May 2018	2,259	444

Data for the period before 2016 are not available. As of this writing, CDPHE is unable to provide a more detailed analysis as to the various types of caregivers, although CDPHE is planning system upgrades in the near future that should remedy this.

However, some caregiver data are available. Recall that, unless CDPHE approves, caregivers are generally limited to offering their services to no more than five patients. In December 2017, the 518 cultivating caregivers reported in Table 6 served an average of 1.9 patients each. Table 7 illustrates the number of caregivers who provided services to more than five patients as of December of the year indicated.

Table 7
Caregivers Serving More Than Five Patients

Year	Caregivers Serving More Than Five Patients
December 2015	12
December 2016	10
December 2017	8

These data show that although there are caregivers serving more than five patients, their number is few and dwindling.

An important limitation to the data presented in Table 6 is the simple fact that, except for transporting and cultivating caregivers, registration is voluntary. Thus, these data should be considered to reflect the fact that as of the dates indicated, there were at least this many caregivers in the state. There were likely more. Additionally, as with other data presented in this sunset report, actual daily figures may fluctuate dramatically, given that registrations are valid for one year from the date of issuance. Thus, caregiver registrations are issued, renewed and expire on a daily basis.

Caregivers are responsible for obtaining copies of the medical marijuana registry identification cards of their patients, and ensuring those registrations are current and unexpired.

Testing Facility Certification

CDPHE also provides laboratory-related services to the regulated marijuana industry and MED, by recommending certification of testing facilities to MED and by administering a proficiency testing program for those facilities. Table 8 illustrates, for the fiscal years indicated, CDPHE's staffing and expenditures associated with these activities.

Table 8
Laboratory Services Medical Marijuana Fiscal Information

Fiscal Year	FTE	Expenditures
15-16	2.0	$220,955
16-17	3.0	$294,217
17-18	7.0	$1,652,216

Data are not available for the period prior to fiscal year 15-16. The surge in spending and staffing in fiscal year 17-18 can be attributed to building, equipping and staffing a new reference laboratory, which, ideally, will create all of the samples used in proficiency testing (discussed below). This should add greater confidence to the proficiency tests, since CDPHE will be creating the test samples. Such a laboratory may also, at some point, be used as a sort of referee for contested test results.

Current CDPHE staff dedicated to the marijuana laboratory testing program include 7.0 FTE:

- 1.0 FTE Physical Science Researcher/Scientist IV: State Marijuana Laboratory Sciences Program Manager. This position supervises staff assigned to the marijuana testing facility inspection program and the marijuana reference laboratory program.
- 1.0 FTE Physical Science Researcher/Scientist II: Marijuana Reference Laboratory Lead Scientist. This position develops, optimizes and applies analytical methodologies to detect and quantify the presence of cannabinoids, pesticides, heavy metals, residual solvents and microbial contaminants in marijuana samples. This position also serves as an assistant to the State Marijuana Laboratory Sciences Program Manager in the marijuana reference laboratory.
- 1.0 FTE Physical Science Researcher/Scientist I: Marijuana Reference Laboratory Quality Assurance Officer. This position applies knowledge of quality assurance, accreditation requirements, scientific principles and analytical skills to continually improve quality and efficiency within the marijuana reference laboratory.

- 2.0 FTE Physical Science Researcher/Scientist I: Marijuana Laboratory Auditor. These positions support the marijuana testing facility inspection program and facilitate the audits and inspections of marijuana testing facilities.
- 1.0 FTE Laboratory Technician I: Marijuana Reference Laboratory Technician. This position prepares and analyzes samples to detect the presence of cannabinoids and prohibited substances in marijuana samples.
- 1.0 FTE Statistical Analyst I: Marijuana Laboratory Sciences Data Analyst. This position coordinates data collection, management, analysis and dissemination of marijuana testing data.

Rules promulgated under the Retail and Medical Marijuana Codes require regulated marijuana to be tested in five categories:

- Microbials (bacteria and fungi),
- Mycotoxins (toxins produced by fungi),
- Residual solvents,
- Pesticides, and
- Potency.

Before a marijuana testing facility can begin accepting samples from MED-licensed businesses, the testing facility must first be licensed and certified by MED. To obtain certification, the testing facility must be recommended for certification by CDPHE in each of the aforementioned testing categories before providing those testing services to MED licensees.

First, the testing facility must be licensed by MED. Next, it must contact CDPHE to begin the approval process.

After the testing facility establishes analytical testing methods and associated standard operating procedures, the first step in the CDPHE process is for the testing facility to conduct an internal self-audit to evaluate compliance with certification requirements. The general self-audit for a testing facility examines:

- Personnel qualifications,
- Standard operating procedures manuals,
- Analytical processes,
- Proficiency testing,
- Quality control and quality assurance,
- Security,
- Sample tracking,
- Specimen retention,
- Laboratory space,
- Records, and
- Results reporting.

Each testing category has its own self-audit requirements specific to the individual category. In general, however, each requires an assessment of the testing facility's:

- Standard operating procedures,
- Validation processes,
- Analytical processes,
- Quality control and quality assurance measures, and
- Reporting requirements.

Once the self-audits are completed and all identified non-conformances are properly addressed and corrected, the testing facility may apply to CDPHE for an inspection. This application process includes submission of the testing facility's quality assurance manuals, standard operating procedures, validation summaries, the qualifications of relevant personnel and payment of the appropriate fee. The cost to obtain approval is $500 for the first testing category and $150 for each additional category.

CDPHE staff then conducts a desk audit of the documents submitted and if they are acceptable, an onsite inspection is conducted. The fee for the desk audit is $150 and the fee for the onsite inspection is $250.

Table 9 illustrates, for the fiscal years indicated, the number of pre-certification inspections CDPHE conducted of marijuana testing facilities.

Table 9
Pre-Certification Inspections of Testing Facilities

Fiscal Year	Potency	Residual Solvents	Microbial	Mycotoxins	Pesticides
13-14	5	0	0	0	0
14-15	12	8	7	0	0
15-16	11	8	11	0	0
16-17	10	12	10	0	0
17-18	12	10	12	0	9

CDPHE did not begin reviewing testing facilities in the categories of mycotoxins or pesticides until early 2018. Thus, no data are available for those categories prior to this time.

Within 15 days of the inspection, CDPHE provides the testing facility with an inspection report. The facility must provide a written plan of correction to address the identified deficiencies to CDPHE within 15 days of receiving the report. CDPHE then reviews the plan and supporting documentation to determine acceptability of the corrective actions. If CDPHE approves of the plan and finds that the testing facility should be certified, it notifies MED of such. If MED grants certification, the facility may begin testing marijuana for MED licensees.

Table 10 illustrates, for the fiscal years indicated, the number of testing facilities receiving positive recommendations from CDPHE.

Table 10
Positive Certification Recommendations of Testing Facilities

Fiscal Year	Potency	Residual Solvents	Microbial	Mycotoxins	Pesticides
13-14	5	0	0	0	0
14-15	10	6	3	0	0
15-16	11	8	12	0	0
16-17	9	9	10	0	0
17-18	12	9	10	0	6

As Table 10 illustrates, testing for mycotoxins and pesticides is just beginning.

If CDPHE does not approve the plan of correction, CDPHE will issue a negative recommendation. Table 11 illustrates, for the fiscal years indicated, the number of negative recommendations it has made to MED.

Table 11
Negative Certification Recommendations of Testing Facilities

Fiscal Year	Number of Negative Certification Recommendations
13-14	0
14-15	9
15-16	3
16-17	2
17-18	1

As the data in Table 11 demonstrate, relatively few testing facilities received negative recommendations.

The data in Tables 9, 10 and 11 do not necessarily add up for several reasons. First, inspection and recommendation processes may cross fiscal years. For example, a facility may have been inspected in June, but the certification recommendation was not made until July. Next, the number of negative certification recommendations reported in Table 11 resulted from both pre-certification inspections and desk audits. For example, a testing facility could apply for a pre-certification inspection, but during the desk audit, CDPHE determined that the facility was not eligible for inspection (and therefore certification) due to significant deficiencies in the facility's processes, systems or methodologies.

Once certified, CDPHE inspects each testing facility for each testing category once each year. Additionally, certified marijuana testing facilities must participate in proficiency testing twice each year in each approved category. The goal of such tests is to ensure that the individual marijuana testing facilities can obtain the same or similar test results to ensure consistency from one testing facility to another. During proficiency testing, CDPHE or a third party prepares a test sample that is then tested by each licensed and approved testing facility. Each facility provides its results to CDPHE.

Table 12 illustrates the date and type of proficiency test conducted between March 2016 and June 2018, as well as the number of testing facilities participating and the results.

Table 12
Proficiency Testing

Date	Test Category	Number of Testing Facilities Participating	100%	80-100%	<80%
3/7/2016	Flower Potency	12	12	0	0
6/1/2016	Flower Potency	12	12	0	0
8/12/2016	Flower Potency	12	12	0	0
6/1/2017	Concentrate Potency	10	7	2	1
6/1/2017	Edibles Potency	10	7	2	1
6/1/2017	Flower Potency	10	7	2	1
12/12/2017	Microbials	10	9	0	1
12/12/2017	Pesticides	9	7	2	0
12/12/2017	Residual Solvents	10	9	0	1
3/9/2018	Flower Potency	12	12	0	0
3/9/2018	Edibles Potency	12	12	0	0
3/9/2018	Concentrate Potency	12	12	0	0
5/24/2018	Microbials	10	10	0	0
5/24/2018	Residual Solvents	10	4	3	3
5/24/2018	Pesticides	10	9	1	0

A result of "<80%" indicates that the testing facility incorrectly identified at least 20 percent of the total number of analytes and thus failed the proficiency test. A result of "80-100%" indicates the testing facility had an incorrect result for one or more individual analytes, but is not considered to be a failed proficiency test. A result of "100%" indicates that the testing facility correctly identified all analytes.

MED rules require licensed testing facilities to participate in proficiency testing with continued satisfactory performance.[111] If a facility receives a result of anything less

[111] 1 CCR § 212-1 M 707(C), Medical Marijuana Code Rules, and 1 CCR § 212-2 R 707(C), Colorado Retail Marijuana Code Rules.

than 100 percent, remedial action must be taken. A score of "<80%" is considered unsatisfactory and may result in license limitation, suspension or revocation.[112] There have been no actions based on these grounds.

Finally, with the passage of House Bill 18-1422, all marijuana testing facilities must also obtain certification by the International Organization for Standardization by January 1, 2019.

Reference Library

Section 25-1.5-106(3.5), Colorado Revised Statutes (C.R.S.), requires CDPHE to establish and maintain a marijuana laboratory testing reference library in an attempt to create marijuana testing standards. In other fields, Standard Testing Methods (analytical methods validated across multiple laboratories) provide a mechanism by which laboratories can ensure consistency from one laboratory to another. However, no Standard Testing Methods yet exist for marijuana. Thus, the reference library consists of a compilation of guidance documents and scientific literature for marijuana testing facilities to utilize in developing their testing protocols.

The reference library is online and can be accessed by testing facilities and the general public alike. It contains links to information on topics such as:[113]

- Microbial pathogens and total yeast and mold,
- Residual solvent testing,
- Pesticide residue testing,
- Potency determination,
- Validation guidelines,
- Marijuana sampling procedures, and
- Mycotoxin testing.

Collateral Consequences – Criminal Convictions

Section 24-34-104(6)(b)(IX), C.R.S., requires the Colorado Office of Policy, Research and Regulatory Reform to determine whether the agency under review, through its licensing processes, imposes any disqualifications on applicants or registrants based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

Section 25-1.5-106(10), C.R.S., stipulates that the medical marijuana registration of a patient convicted of a criminal offense under Title 18, C.R.S., or ordered by a court to treatment for substance use disorder, or sentenced to the Division of Youth Corrections

[112] 1 CCR §§ 212-1 M 707(G, H and I), Medical Marijuana Code Rules, and 1 CCR §§ 212-2 R 707(G, H and I), Colorado Retail Marijuana Code Rules.
[113] Colorado Department of Public Health and Environment. *Marijuana reference library*. Retrieved July 12, 2018, from www.colorado.gov/pacific/cdphe/marijuana-reference-library

is subject to immediate renewal. In other words, the registration is effectively summarily revoked, but the patient may immediately seek renewal.

No data regarding any revocations are available for the years prior to 2016. While 20 registrations have been revoked since 2016, CDPHE has not tracked the grounds for those revocations. Thus, it is not possible to ascertain whether they were revoked due to the patient having a criminal conviction.

Analysis and Recommendations

Recommendation 1 – Continue the medical marijuana program at the Colorado Department of Public Health and Environment for nine years, until 2028.

On November 7, 2000, the voters of Colorado passed Amendment 20 to the state's constitution, effectively decriminalizing the medical use of marijuana. Amendment 20 became effective on December 28, 2000.

In short, this constitutional provision:

- Creates an affirmative defense for any patient, and the patient's primary caregiver, whose physician has diagnosed the patient as having a debilitating medical condition, and whose physician has advised the patient that the patient might benefit from the use of medical marijuana;[114]
- Provides for the creation of a medical marijuana registry, including requirements for inclusion on the medical marijuana patient registry and the issuance of registry identification cards;[115]
- Enumerates the debilitating medical conditions for which patients may be granted medical marijuana registry identification cards[116] and creates a mechanism by which the state health agency can add to this list; [117]
- Generally limits possession of medical marijuana to no more than two ounces of marijuana in a useable form and no more than six plants;[118] and
- Generally applies only to patients who are at least 18 years old.[119]

The Amendment also directed the Governor to designate a "state health agency" to establish[120] and maintain the medical marijuana registry and to promulgate rules to administer such program. On February 5, 2001, the Governor designated the Colorado Department of Public Health and Environment (CDPHE) as the state health agency responsible for implementing the amendment.[121]

Amendment 20 also directed the General Assembly to enact legislation to implement the amendment. House Bill 01-1371 served this purpose by, among other things, authorizing the creation and maintenance of the medical marijuana registry. The General Assembly granted CDPHE broad rule-making authority to promulgate the registry application forms, the processes for issuing medical marijuana registry cards and the manner in which CDPHE could consider adding to the list of debilitating medical conditions outlined in Amendment 20.

[114] Colo. Const. Art. XVIII, § 14(2)(a).
[115] Colo. Const. Art. XVIII, § 14(3).
[116] Disabling medical conditions were created by the General Assembly in Senate Bill 17-017.
[117] Colo. Const. Art. XVIII, § 14(1)(a).
[118] Colo. Const. Art. XVIII, § 14(4).
[119] Colo. Const. Art. XVIII, § 14(6).
[120] Colo. Const. Art. XVIII, § 14(7).
[121] Colorado Executive Order D 001 01, signed February 5, 2001.

The first sunset criterion asks,

> Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation[.][122]

In this case, it is legitimate to ask whether the system created under section 25-1.6-106, Colorado Revised Statutes (C.R.S.), which requires, among other things, a bona fide physician-patient relationship before a patient can register with the medical marijuana registry, serves to protect the public. In other words, is public protection enhanced by requiring physician involvement in determining whether medical marijuana is appropriate for individual patients, as well as the amount of marijuana to which such patients should be entitled?

Amendment 20 and the medical marijuana program under sunset review here predate Amendment 64, which legalized marijuana for recreational use. Prior to the passage of Amendment 64, the enactment of the Colorado Retail Marijuana Code (Retail Code) and the prevalence of retail marijuana in the state, this question might have been easier to answer. With retail marijuana readily available in many parts of the state, does requiring a physician-patient relationship and patient registration create an undue burden in the context of medical marijuana?

However, the consumer of medical marijuana is a patient with a debilitating or disabling medical condition. As such, it seems reasonable to require initial and continued physician involvement in the treatment of such patients.

Some argue that the physician-patient relationship is little more than a ruse, and that physicians who recommend medical marijuana do not actually examine their patients or develop any sort of relationship with them. On the other hand, some argue that the bona fide physician-patient relationship articulated in statute goes beyond that required in the ordinary course of the practice of medicine, where a five-minute visit to the hospital emergency department may suffice for the treatment of other conditions or the prescription of other medications. This tension tends to argue that perhaps the proper balance has been reached and that physician involvement in recommending medical marijuana is not overly burdensome.

Regardless, the medical marijuana program is explicitly required by Amendment 20 itself, which requires the creation of a medical marijuana patient registry, requires the Governor to designate a state health agency to maintain that registry and requires the General Assembly to pass implementing legislation. Section 25-1.5-106, C.R.S., the subject of this sunset report, satisfies these requirements. If it were to sunset, the General Assembly would be required to pass new legislation to replace it and to accomplish, for the most part, exactly what it does today.

[122] § 24-34-104(6)(b), C.R.S.

Therefore, the General Assembly should continue the medical marijuana program for nine years, until 2028.

Recommendation 2 – Clarify that medical marijuana registry identification cards are subject to immediate revocation, not renewal, upon a patient's conviction for violating the state Controlled Substances Act and sentencing to substance abuse treatment or the Division of Youth Services, and clarify that application for renewal is permissive, not mandatory.

Section 25-1.5-106(10), C.R.S., states:

> Any patient who is convicted of a criminal offense under Article 18 of Title 18[, C.R.S.,] who is sentenced or ordered by a court to treatment for a substance use disorder, or sentenced to the Division of Youth Services, is subject to immediate renewal of his or her patient registry identification card, and the patient shall apply for the renewal based upon a recommendation from a physician with whom the patient has a bona fide physician-patient relationship.

The clear intent of this provision is to provide CDPHE the opportunity to immediately review a patient's application upon conviction and sentencing to substance abuse treatment, in order to ascertain whether the patient should remain on the registry or be removed.

However, the phrasing is confusing in the sense that it does not directly state that a registration is subject to revocation. Rather it states that it is subject to immediate renewal, which then forces the patient to submit a renewal application in order to remain on the registry. Confusion could be reduced by replacing the word "renewal" with "revocation" to indicate the actual process.

Finally, the statute also mandates that the patient "shall apply for the renewal." However, this mandate is unenforceable and seems contrary to public policy in that no other population is mandated to apply to the registry. It should be up to the patient to decide whether to apply for renewal.

Therefore, the General Assembly should clarify that registrations are revoked upon a patient's conviction for violating the state Controlled Substances Act and sentencing to substance abuse treatment or the Division of Youth Services, and that any application for renewal is discretionary on the part of the patient.

Recommendation 3 – Clarify that while licensed mental health providers can diagnose post-traumatic stress disorder, only physicians can recommend the use of medical marijuana in its treatment.

Patients diagnosed with a disabling medical condition may have medical marijuana recommended to them for treatment of the condition. Statute defines a disabling medical condition as "post-traumatic stress disorder as diagnosed by a licensed mental health provider or physician."[123]

While the term "licensed mental health provider" appears nowhere else in the statute, the statute explicitly states that physicians can recommend medical marijuana for the treatment of such a condition.[124] Therefore, it is reasonable to infer that only physicians can make such recommendations. Indeed, this is commonly recognized to be the case.

However, the definition of disabling medical condition has confused some into thinking that licensed mental health providers can recommend medical marijuana for the treatment of such a condition. Since this is inaccurate, the General Assembly should clarify that while both physicians and licensed mental health providers can diagnose such a condition, only physicians can actually recommend the use of medical marijuana in the treatment of such a condition.

Recommendation 4 – Amend the definition of primary caregiver to clarify that a parent of a minor with a disabling medical condition must serve as that minor's primary caregiver.

Amendment 20 created the notion of debilitating medical conditions, enumerated them and created the framework whereby the parent of a minor with a debilitating medical condition must serve as the primary caregiver to that child:

> . . . no patient under [18] years of age shall engage in the medical use of marijuana unless [ ] A parent residing in Colorado consents in writing to serve as a patient's primary care-giver;[125]

In defining the term "primary caregiver," the General Assembly specifically referred to this requirement by including in the statutory definition,

> A parent of a child as described by subsection (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;[126]

[123] § 25-1.5-106(2)(a.7), C.R.S.
[124] § 25-1.5-106(2.5)(d)(II), C.R.S.
[125] Colo. Const. Art. XVIII, § 14(6)(e).
[126] § 25-1.5-106(2)(d.5)(I), C.R.S.

Thus, the definition of caregiver is limited to the context of debilitating medical conditions.

Senate Bill 17-017 (SB 17) established the notion of disabling medical conditions, and, like Amendment 20, clearly requires a parent of a minor child suffering from such a condition to serve as that child's primary caregiver:

> . . . no patient with a disabling medical condition under [18] years of age shall engage in the medical use of marijuana unless [ ] a parent residing in Colorado consents in writing to serve as the patient's primary caregiver;[127]

However, in an apparent oversight, SB 17 failed to amend the definition of primary caregiver to include the parents of children with disabling medical conditions.

Since it is clear that the General Assembly intended for parents of children with disabling medical conditions to serve as their primary caregivers, the General Assembly should specify this in the definition of primary caregiver.

Recommendation 5 – Include in the definition of a bona fide physician-patient relationship, the requirement that the physician explain the possible risks and benefits of medical marijuana to a minor patient and to each of the minor's parents.

Amendment 20 created the notion of debilitating medical conditions, enumerated them and created the framework whereby a minor with a debilitating medical condition may use medical marijuana, provided that, among other things,

> (a) Two physicians have diagnosed the patient as having a debilitating medical condition; (b) One of the physicians referred to in paragraph (6)(a) has explained the possible risks and benefits of medical use of marijuana to the patient and *each of the patient's parents residing in Colorado*; [emphasis added][128]

Senate Bill 17 established the notion of disabling medical conditions, and, like Amendment 20, clearly permits a minor child suffering from such a condition to use medical marijuana, provided that, among other things,

> (I) Two physicians, one of whom must be a board-certified pediatrician, a board-certified family physician, or a board-certified child and adolescent psychiatrist and attest that he or she is part of the patient's primary care provider team, have diagnosed the patient as having a disabling medical condition; [and] (II) One of the physicians referred to in subsection (2.5)(i)(I) of this section has explained the possible risks and benefits of the

[127] § 25-1.5-106(2.5)(i)(V), C.R.S.
[128] Colo. Const. Art. XVIII, §§ 14(6)(a and b).

> medical use of marijuana to the patient and *each of the patient's parents residing in Colorado*; [emphasis added][129]

However, in an apparent oversight, the statutory definition of bona fide physician-patient relationship requires only physician consultation with the patient. It does not specify that consultation with a minor's parents is also required.[130]

Since it is clear that the General Assembly intended for physicians of minor patients with debilitating and disabling medical conditions to consult with the parents of those patients, the General Assembly should amend the definition of bona fide physician-patient relationship to reflect this requirement.

Recommendation 6 – Clarify that medical marijuana registry information pertaining to patients with disabling medical conditions is provided the same confidentiality protections as information pertaining to patients with debilitating medical conditions.

Amendment 20 provides rigorous confidentiality language surrounding information contained in the medical marijuana registry:

> No person shall be permitted to gain access to any information about patients in [CDPHE's] confidential registry, or any information otherwise maintained by [CDPHE] about physicians and primary care-givers, except for authorized employees of [CDPHE] in the course of their official duties and authorized employees of state or 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 or its functional equivalent . . .[131]

Section 25-1.5-106(7)(d), C.R.S., while primarily addressing caregivers, also implements the confidentiality provision of Amendment 20 by addressing the release of caregiver and patient information to law enforcement. In doing so, it provides:

> . . . If the person is a registered patient or primary caregiver, [CDPHE] may not release information unless consistent with section 14 of article XVIII of the state constitution . . .

Since the constitution speaks only to patients with debilitating medical conditions, this reference to the constitution has led some to conclude that patient and caregiver information is protected only when a debilitating medical condition is involved, and does not include a disabling medical condition.

[129] §§ 25-1.5-106(2.5)(i)(I and II), C.R.S.
[130] *See* § 25-1.5-106(2)(a.5)(II), C.R.S.
[131] Colo. Const. Art. XVIII, § 14(3)(a).

Since this was an apparent oversight, the General Assembly should clarify that patients and their caregivers enjoy the same protections in terms of the confidentiality of their information, regardless of whether they suffer from a debilitating or disabling medical condition.

Recommendation 7 – Repeal section 25-1.5-106(3.7), C.R.S.

Section 25-1.5-106(3.7), C.R.S., requires CDPHE to convene a working group to explore testing options for marijuana grown outside of MED's licensed system. Although no documentation could be located pertaining to this group, it did meet and may have contributed to the passage of House Bill 17-1367, which enables patients and caregivers who are participating in medical research studies to have their medical marijuana tested.

The group is now inactive.

Since the group met, produced tangible results and is now inactive, it should be repealed.

Recommendation 8 – Make technical changes.

As with any law, the statute governing the medical marijuana program contain instances of obsolete, duplicative and confusing language, and the statute should be revised to reflect current terminology and administrative practices. These changes are technical in nature, so they will have no substantive impact.

The General Assembly should make the following technical changes:

- **Section 25-1.5-106(3)(b)(III), C.R.S.** This section, which allows CDPHE to develop a form that constitutes "written documentation" for use when recommending medical marijuana, should be repealed, since it is inconsistent with and partially redundant of section 25-1.5-106(3)(a)(IV), C.R.S., which mandates such development.
- **Section 25-1.5-106(3.5)(d), C.R.S.** Repeal the date associated with this directive, since it has come and gone, but retain the substantive requirement.
- **Section 25-1.5-106(3.8)(b), C.R.S.** Repeal this provision since the articulated duties have been performed and the target date has come and gone.
- **Sections 25-1.5-106(5)(c), (6)(a) and (6)(c), C.R.S.** House Bill 10-1260 changed the name of the Colorado State Board of Medical Examiners to the Colorado Medical Board. Section 25-1.5-106, C.R.S., should be amended to reflect this change.
- **Section 25-1.5-106(6)(a), C.R.S.** This section should be amended to reference subsection (3), rather than subsection (2), since subsection (3) authorizes the promulgation of the rules referred to.

Administrative Recommendation 1 – CDPHE should allow caregivers to register via hard copy application.

In January 2017, CDPHE launched an online application process for the medical marijuana registry. This is not only the system through which patients receive their medical marijuana registry identification cards, but is also the system through which caregivers register their demographic information to obtain a caregiver registration card.

While CDPHE is to be commended for its attempts to streamline the registration process, there have been some unintended consequences that must be addressed.

Even with the convenience of the online system, patients retain the ability to apply to the registry via hard copy application. This has proven invaluable for patients who may lack the technical knowledge to successfully navigate the online system, but also for those with no or poor access to the internet.

However, caregivers lack a hard copy registration option. Rather, they must register using the online system. This has proven particularly difficult for those individuals with no internet access, as well as to those in areas with poor internet access.

CDPHE, to its credit, has assisted these individuals in registering over the phone. However, this is not only an inefficient use of staff time, but is an inconvenience for the caregiver seeking to register. Additionally, caregiver card expiration notifications can still be hindered when the caregiver lacks even an email address to receive the renewal notification.

Therefore, CDPHE should allow caregivers to register via hard copy application.

Administrative Recommendation 2 – CDPHE should track registry disqualifications based on criminal history.

During the 2013 legislative session, the General Assembly added a criterion to those that govern the research and reporting in sunset reviews. Section 24-34-104(6)(b)(IX), C.R.S., asks,

> Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to paragraph (a) of subsection (5) of this section shall include data on the number of licenses or certifications that the agency denied, revoked, or suspended based on a disqualification and the basis for the disqualification.

Because it is a newer reporting requirement, some programs and organizations, do not track this information. Because the General Assembly finds this information to be an important function of a sunset review, CDPHE should track registration disqualifications for patients on the medical marijuana registry based on past criminal history.

Administrative Recommendation 3 – CDPHE should re-examine the process for adding to the list of debilitating medical conditions.

In enumerating the list of debilitating medical conditions for which medical marijuana may be used, Amendment 20 allows for the delineation of additional conditions by directing the state health agency, which is CDPHE, to develop a process to add to the list. CDPHE has created a process that is rigorous, according to some, and impossible, according to others.

The rules require peer-reviewed published studies of randomized controlled studies or well-designed observational studies showing the efficacy of the use of medical marijuana in humans for the condition that is the subject of the petition. On its face, this requirement appears reasonable. There should be scientifically demonstrable evidence to support the use of medical marijuana for a particular medical condition.

However, the rules lack flexibility and instead dictate what must happen if such studies are not available. This is particularly problematic when discussing marijuana given its status under federal law. There is a remarkable dearth of the studies required by the rule.

As a result, a total of 10 petitions have been submitted requesting the approval of 15 distinct conditions, yet only two—post-traumatic stress disorder (PTSD) and Tourette's syndrome—were referred to the Board of Health to consider the initiation of rulemaking proceedings to add them to the list of debilitating conditions. None have been added to the list, although the General Assembly created the concept of a disabling medical condition to enable sufferers of PTSD to legally use medical marijuana in the treatment of that condition.

With more states legalizing both recreational and medical use of marijuana, it is reasonable to conclude that such studies will be conducted in the near future. But those studies may take years to complete and produce results. In the meantime, patients may be denied medical marijuana that may benefit them.

Therefore, CDPHE should re-examine the process for adding to the list of debilitating medical conditions to, at a minimum, build in some flexibility for the review of petitions.