

Medical Marijuana Regulatory System

Part II

**Department of Public Health and
Environment
Department of Revenue**

**Performance Audit
June 2013**



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is to improve government for the people of Colorado.*



June 25, 2013

Members of the Legislative Audit Committee:

This report contains the results of a performance audit of Colorado's medical marijuana regulatory system. The audit was conducted pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government. This second of two reports presents our findings, conclusions, and recommendations and the responses of the Department of Public Health and Environment and the Department of Revenue. The first report was released in March 2013.



We Set the Standard for Good Government

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MEDICAL MARIJUANA REGULATORY SYSTEM,

PART II

Performance Audit, June 2013

Report Highlights



Dianne E. Ray, CPA
State Auditor

Department of Public Health and Environment
Department of Revenue

PURPOSE

Assess the Department of Public Health and Environment's (Public Health) process for issuing red cards, which give individuals access to medical marijuana, the reasonableness of fees charged to patients, and the State's regulation of caregivers.

BACKGROUND

- In 2000, Colorado voters approved Amendment 20, a constitutional amendment that legalized the medical use of marijuana for patients diagnosed with certain debilitating medical conditions.
- As of March 2013, about 108,000 patients in Colorado had valid red cards.
- Public Health maintains the confidential Medical Marijuana Registry (Registry) containing information related to medical marijuana patients.
- Primary caregivers supply marijuana to a patient but must also assume significant responsibility for managing the patient's well-being. As of December 2012, about 5,400 caregivers were serving about 8,500 patients.
- Public Health's funding to administer the medical marijuana program comes primarily from red card application fees.

OUR RECOMMENDATIONS

The Department of Public Health and Environment should:

- Improve its oversight of physicians recommending medical marijuana.
- Improve the timeliness of processing red card applications.
- Work with the Department of Revenue to strengthen oversight of caregiver activities.
- Ensure the confidentiality of the Registry.
- Improve its management of the Medical Marijuana Cash Fund.
- Improve its controls over expenses.

The Department of Revenue should:

- Work with Public Health to strengthen oversight of caregiver activities.

The departments generally agreed with all of our recommendations.

AUDIT CONCERN

Public Health's controls over access to medical marijuana do not provide assurance that only qualified individuals receive red cards. Public Health has also set its fees too high, resulting in a fund balance that far exceeds the program's needs. In addition, the State has not developed an effective mechanism to oversee caregivers.

KEY FACTS AND FINDINGS

- Public Health does not sufficiently oversee physicians who make medical marijuana recommendations. We found evidence suggesting that some physicians may be making inappropriate recommendations.
 - As of October 2012, a total of 903 physicians had recommended medical marijuana for the 108,000 patients holding valid red cards. Twelve physicians recommended medical marijuana for 50 percent of those patients, including one physician with more than 8,400 patients on the Registry.
 - Some physicians have recommended what appear to be higher-than-reasonable amounts of medical marijuana. In one case, a physician recommended 501 plants for a patient. In another case, a physician recommended 75 ounces of useable marijuana for the patient.
- Public Health has not established a process for caregivers to indicate the significant responsibilities they are assuming for managing the well-being of their patients or for documenting exceptional circumstances that require a caregiver to take on more than five patients.
- Public Health failed to issue red cards within the constitutionally required 35-day time frame for more than one-third of red cards that were valid as of December 2012. However, by May 2013 the process had improved to 99 percent of applications processed within the 35-day time frame.
- It is not clear whether Public Health was adhering to the Colorado Constitution when it allowed staff of contract firms and other state agencies to access the confidential Registry.
- Legal restrictions on Registry access create barriers for law enforcement agencies to effectively and efficiently enforce the State's medical marijuana laws.
- The Medical Marijuana Cash Fund has been out of compliance with a statutory limit on cash fund uncommitted reserves every year since Fiscal Year 2004. At the end of Fiscal Year 2012, the fund had excess uncommitted reserves of more than \$11.3 million, the highest amount of excess uncommitted reserves of any cash fund in the State subject to the requirement.

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RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
1	33	Improve oversight of physician recommendations for medical marijuana by: (a) developing a risk-based approach to conduct positive confirmations; (b) revising the physician certification form to require the cause of the patient's qualifying medical condition, the reason for recommending any marijuana amounts above the standard counts, and an attestation of not having financial ties with any medical marijuana business; (c) working with the Colorado Medical Board to determine risk factors to establish potentially inappropriate recommendations and guidelines related to investigations of physicians; (d) routinely analyzing data from the Medical Marijuana Registry and conducting research to identify physicians that should be investigated; (e) conducting research to identify physicians that should be investigated for having financial ties with medical marijuana businesses, conducting hearings for such physicians, and seeking statutory change if more authority is needed; and (f) placing information on appropriate dosing of marijuana for medical use on the website.	Department of Public Health and Environment	a. Agree b. Agree c. Agree d. Agree e. Partially Agree f. Agree	a. December 2013 b. January 2014 c. March 2014 d. March 2014 e. July 2014 f. July 2014
2	39	Improve the timeliness of processing Medical Marijuana Registry applications by: (a) implementing methods to track the timeliness of individual applications and information on problem applications; (b) establishing clear criteria on which problem applications are subject to the 35-day deadline and implementing other deadlines for problem cases; (c) monitoring the timeliness of individual applications and analyze the causes of untimely processing; (d) monitoring whether "lean" efforts are enhancing efficiency and undertaking more projects as needed; and (e) implementing and reporting on a performance measure on timely processing of applications.	Department of Public Health and Environment	a. Agree b. Agree c. Agree d. Agree e. Agree	a. September 2013 b. September 2013 c. September 2013 d. December 2013 e. August 2013

RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
3	45	Work with the Department of Revenue and stakeholders to determine if Public Health can discontinue maintaining information on medical marijuana dispensaries. If the determination is that this information is not necessary, discontinue collecting it and work with the General Assembly, as necessary, to revise statute to implement this change.	Department of Public Health and Environment	Agree	May 2014
			Department of Revenue	Agree	July 2014
4	53	Strengthen the oversight of caregivers by: (a) implementing procedures to ensure that caregivers meet all legal requirements; (b) approving waivers for caregivers to serve more than five patients only when exceptional circumstances exist; and (c) working with Revenue to determine whether additional criteria are needed to differentiate caregivers from businesses, implement methods to determine whether an individual is a caregiver or a business, and work with the General Assembly as necessary to implement any proposed changes.	Department of Public Health and Environment	a. Agree b. Agree c. Partially Agree	a. January 2014 b. December 2013 c. December 2013
5	55	Work with the Department of Revenue and stakeholders to: (a) evaluate the need to continue to collect information on which caregivers have been designated by individuals as their providers and ensuring any information maintained is updated and accurate; and (b) determine whether Public Health or Revenue needs greater statutory authority to effectively regulate caregivers and if so, present proposed changes to the General Assembly as necessary.	Department of Public Health and Environment	a. Partially Agree b. Partially Agree	a. June 2013 b. December 2013
			Department of Revenue	a. Agree b. Partially Agree	c. July 2014 d. July 2014

RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
6	69	Ensure the confidentiality of the Medical Marijuana Registry by: (a) seeking guidance from the Attorney General on what constitutes an “authorized employee” who can be given access to the Registry and work with the General Assembly if needed to define “authorized employee” in statute; (b) seeking guidance from the Attorney General on whether protected Registry information includes pending applications and work with the General Assembly if needed to clarify statute; (c) seeking guidance from the Attorney General on what confidential Registry information Public Health has authority to provide to law enforcement and work with the General Assembly if needed to clarify statute; (d) ensuring that all contracts involving the Registry are complete and accurate and amending, as needed, contracts with Denver Health and Hospital Authority; (e) revising the policy for handling confidentiality breaches to allow the notification of affected parties in a way that minimizes further compromise of confidentiality; and (f) ensuring that staff take proper precautions to protect confidential data and follow policies when breaches of confidentiality occur.	Department of Public Health and Environment	a. Agree b. Agree c. Agree d. Agree e. Agree f. Agree	a. June 2014 b. December 2013 c. December 2013 d. December 2013 e. December 2013 f. September 2013
7	76	Improve the Medical Marijuana Registry’s general computer controls by: (a) developing a system to record which fields were modified by a user to provide historical information on key fields; (b) identifying fields that require data input controls and implementing those controls; (c) developing a method to identify physicians who are no longer eligible to recommend medical marijuana; (d) creating a disaster recovery plan that incorporates all critical components and complies with Colorado Information Security Policies; and (e) encrypting all backups of Registry data and storing the backups off-site.	Department of Public Health and Environment	a. Partially Agree b. Partially Agree c. Partially Agree d. Agree e. Agree	a. May 2014 b. May 2014 c. May 2014 d. July 2013 e. December 2013

RECOMMENDATION LOCATOR

Rec. No.	Page No.	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
8	84	Improve management of the Medical Marijuana Cash Fund by: (a) suspending or reducing the Medical Marijuana Registry application fee until the excess reserve balance is in compliance with statutory requirements; (b) developing and including in the Fiscal Year 2015 budget request a proposal to further reduce the Cash Fund's excess reserve balance and work with the General Assembly as needed to implement the proposal; and (c) annually reviewing the reasonableness of the application fee, including any excess reserves in the Cash Fund, and making timely recommendations for changes to the Board of Health.	Department of Public Health and Environment	a. Agree b. Agree c. Agree	a. January 2014 b. October 2013 c. December 2013
9	88	Improve controls over expenses from the Medical Marijuana Cash Fund by: (a) allocating shared direct expenses appropriately; (b) following State Fiscal Rules, State Personnel Rules, and department policies and procedures for expenses; and (c) ensuring that all staff who review, approve, and allocate expenses have training on applicable policies and procedures.	Department of Public Health and Environment	a. Agree b. Agree c. Agree	a. December 2013 b. July 2013 c. September 2013

Overview of Colorado's Medical Marijuana System

Chapter 1

In 2000, Colorado voters approved Amendment 20, a constitutional amendment that legalized the medical use of marijuana for patients diagnosed with certain debilitating medical conditions, including cancer, glaucoma, positive status for human immunodeficiency virus (HIV), or acquired immune deficiency syndrome (AIDS). The Colorado Constitution (art. XVIII, sec. 14) also allows for the medical use of marijuana to alleviate symptoms of chronic or debilitating diseases or medical conditions, or treatment for such conditions, including cachexia (general ill health with emaciation), severe pain, severe nausea, seizures, or persistent muscle spasms. Throughout this report, we will use the term “medical marijuana.” It is important to note, however, that we have not found information indicating that “medical” marijuana is a substantively different product than marijuana used for recreational purposes.

Although voters passed Amendment 20 in 2000, the General Assembly did not establish a regulatory framework for medical marijuana for nearly a decade. In the early 2000s, the federal government, under the Bush Administration, began conducting well-publicized drug enforcement activities, such as raids of medical marijuana businesses, which may have influenced states with laws legalizing medical marijuana use to delay administering their medical marijuana programs. The Obama Administration, however, took a different approach. In October 2009, that administration issued the “Ogden memo,” which advised federal prosecutors not to focus their federal drug enforcement resources on individuals complying with state medical marijuana laws. Following issuance of the Ogden memo, the number of storefront retail locations, called dispensaries, that sell medical marijuana increased in Colorado. Amendment 20 did not contemplate the possible existence of dispensaries but rather focused on requirements for patients to grow and cultivate medical marijuana themselves or obtain it from individuals called primary caregivers (caregivers). Therefore, in response to the upsurge of dispensaries, the General Assembly passed the Colorado Medical Marijuana Code (House Bill 10-1284) in 2010. That bill established a system of statewide regulations governing the production and sale of marijuana for medical use.

Federal law does not recognize the lawful use of marijuana for any purpose. Nonetheless, 18 states and the District of Columbia have passed state laws legalizing the use of medical marijuana.

History of Medical Marijuana Legislation

As the enabling law for Colorado's medical marijuana system, Amendment 20 established certain requirements that focused primarily on activities related to medical marijuana patients. Specifically, Amendment 20:

- Defined the debilitating medical conditions for which patients can use medical marijuana.
- Provided that patients can only receive a recommendation to use medical marijuana from a physician with whom they have a "bona fide relationship."
- Outlined requirements for the issuance of medical marijuana cards, also referred to as "red cards" because of the red-colored ink that appears on the cards. Red cards serve as official state documentation that patients have been authorized to obtain, possess, and use marijuana for medical purposes.
- Required the Colorado Department of Public Health and Environment (Public Health) to establish and maintain a confidential Medical Marijuana Registry (the Registry) containing information related to medical marijuana patients.
- Established an affirmative defense for patients, physicians, and caregivers who are charged with violating state criminal laws related to marijuana.

To strengthen the legal framework for Colorado's medical marijuana system, the General Assembly enacted a series of medical marijuana-related laws starting in 2001. Two state departments—the Department of Revenue (Revenue) and Public Health—share responsibility for implementing the provisions of these laws. The most comprehensive legislation was passed during the 2010 and 2011 Legislative Sessions. The following bullets describe key aspects of the State's medical marijuana laws.

- **Colorado Medical Marijuana Code (House Bill 10-1284):** Established the State's primary framework for licensing and regulating medical marijuana businesses. The bill addressed various programmatic aspects of administering Colorado's medical marijuana system and specified duties for Revenue and Public Health. For example, the bill required patients to indicate on their red card applications how they would acquire their medical marijuana, and it limited how many patients can use the same caregiver. House Bill 10-1284 also outlined requirements for licensing medical marijuana businesses and placed a statewide moratorium on new

medical marijuana business license applications from August 1, 2010, through June 30, 2011. In addition, the bill allowed local authorities to adopt a resolution or ordinance by July 1, 2011, to license, regulate, or prohibit medical marijuana businesses that cultivate and sell medical marijuana within local jurisdictions.

- **Physician–Patient Relationship (Senate Bill 10-109):** Established Public Health’s oversight responsibilities related to physicians and patients participating in Colorado’s medical marijuana system. For example, it required that patients have a “bona fide” relationship with a physician before the physician could recommend medical marijuana for the patient. The bill also required that physicians meet certain other requirements before making medical marijuana recommendations such as having a valid, unrestricted Colorado medical license in good standing and not having a financial interest in a medical marijuana business. Finally, the bill gave Public Health and the Colorado Medical Board authority to pursue enforcement actions against physicians who violate constitutional, statutory, or regulatory provisions related to medical marijuana.
- **Medical Marijuana Businesses (House Bill 11-1043):** Extended for a second year the moratorium on new medical marijuana businesses, which was originally established by House Bill 10-1284. This bill specified that individuals could apply for new medical marijuana business licenses on or after July 1, 2012, which became the new end date of the moratorium. In addition, the bill further defined requirements affecting patients and caregivers. For example, the bill specified circumstances when patients can legally purchase medical marijuana prior to being issued their red cards. House Bill 11-1043 also required caregivers to register the location of their medical marijuana cultivation operations with Revenue.
- **Medical Marijuana Business Licensing (House Bill 13-1238):** Allows medical marijuana businesses to operate with a conditional state license while their license application with the relevant local authority is pending. Previously, businesses had been required to obtain a local business license before they could receive a state business license. These changes to the medical marijuana business licensing process were in response to business licensing delays we discussed in our *Medical Marijuana Regulatory System, Part I Performance Audit* (March 2013). The bill also added reporting requirements for Revenue related to medical marijuana business licenses.

Two bills that established key statutory requirements for Colorado’s medical marijuana system—House Bill 10-1284 and Senate Bill 10-109—include provisions that require sunset reviews and, ultimately, the repeal of both laws. Specifically, House Bill 10-1284 requires a sunset review of Revenue’s medical

marijuana-related activities prior to the law's repeal on July 1, 2015. Similarly, Senate Bill 10-109 requires a concurrent sunset review of Public Health's Medical Marijuana Program and the Colorado Medical Board. The bill also specifies that the Medical Marijuana Program at Public Health will be repealed on July 1, 2019.

Amendment 64

In November 2012, Colorado voters passed Amendment 64, which legalized the use of recreational marijuana for adults who are at least 21 years of age. During the 2013 Legislative Session, the General Assembly enacted two bills related to regulation of Colorado's recreational marijuana industry. House Bill 13-1317 established regulatory requirements for recreational marijuana businesses and renamed the Medical Marijuana Enforcement Division at Revenue as the Marijuana Enforcement Division. The newly named division's responsibilities were expanded to include oversight of both the medical and recreational marijuana industries in Colorado. The regulatory model for recreational marijuana businesses will be similar to that for medical marijuana businesses, and certain requirements were established to regulate business owners involved with both marijuana industries. For example, House Bill 13-1317 allows individuals to operate medical and recreational marijuana businesses in the same location. However, the businesses must maintain actual physical separation, and the business owner must obtain approval for that arrangement from the local jurisdiction where the businesses are located. Individuals who have been operating a medical marijuana business with an approved or pending state license can apply for a retail marijuana establishment license to sell recreational marijuana beginning on October 1, 2013. Other individuals may apply for licensure on and after July 1, 2014. Finally, House Bill 13-1317 requires a sunset review of Revenue's recreational marijuana-related activities prior to the repeal of the State's recreational marijuana regulatory statutes as of July 1, 2016.

House Bill 13-1318 established sales and excise taxes on recreational marijuana, subject to voter approval during the statewide election in November 2013.

It is unclear how the passage of Amendment 64 will affect the medical marijuana industry. For example, individuals may decide that it is more convenient to purchase recreational marijuana rather than apply for a red card to buy medical marijuana. If a significant number of individuals make this determination, then the medical marijuana industry may noticeably shrink. Conversely, there are several factors that may allow the medical marijuana industry to survive. First, it is unclear how the federal government will respond to the legalization of marijuana for recreational use by Colorado (and Washington State). If, for example, the federal government makes efforts to block implementation of Amendment 64, then the demand for medical marijuana may not change significantly. Second, if voters approve the plan devised by the General Assembly in House Bill 13-1318, recreational marijuana will be taxed at a significantly

higher rate than medical marijuana, which may encourage individuals to continue using medical marijuana if it costs significantly less than recreational marijuana. Finally, Amendment 64 does not legalize the recreational use of marijuana for individuals under the age of 21, so they would not be able to obtain marijuana unless they have a debilitating condition that qualifies them for a red card.

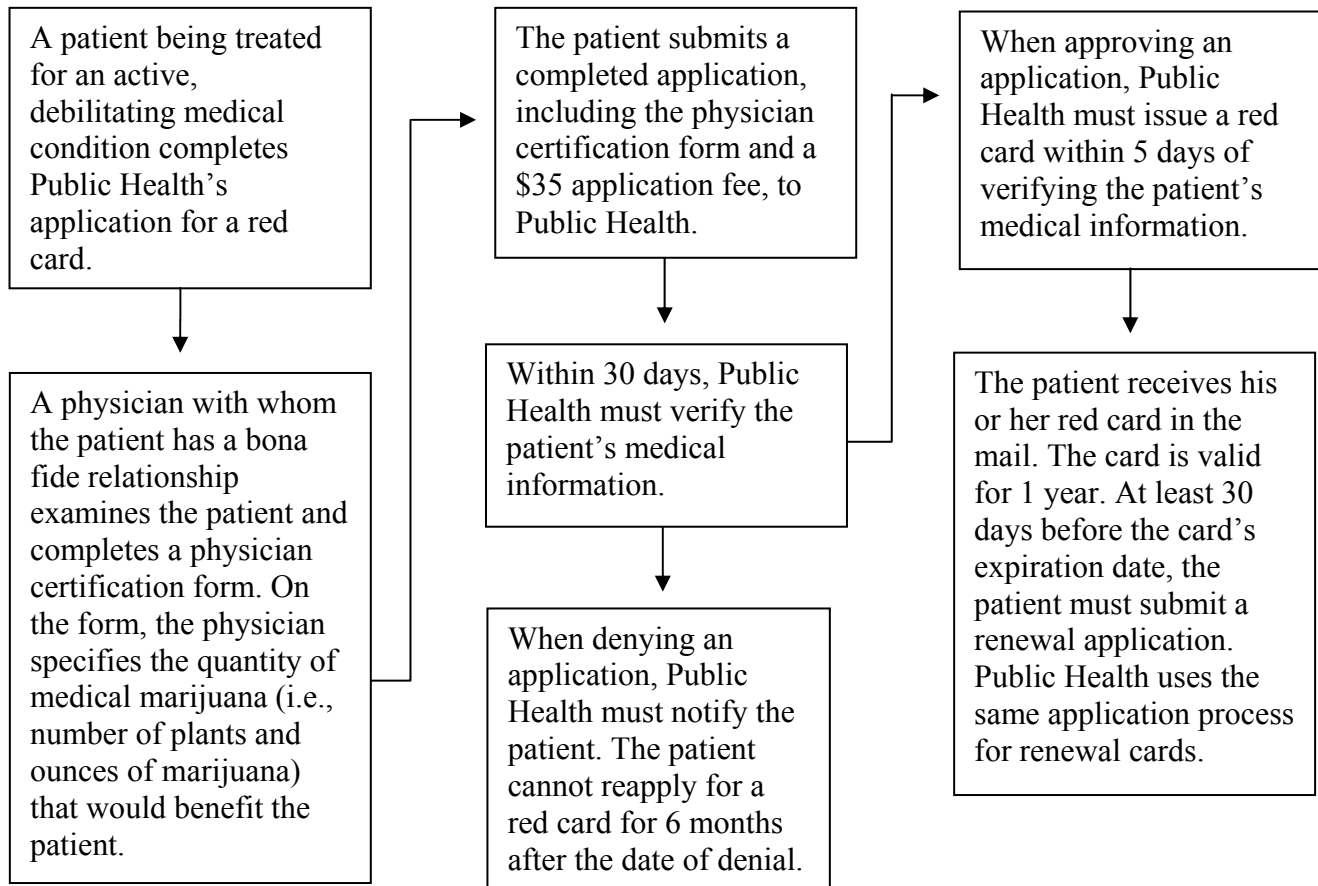
Although Amendment 64 and the 2013 legislation related to recreational marijuana were enacted during our audit process, the scope of this audit focused only on Colorado's medical marijuana system, which, as discussed above, is likely to remain relevant for the foreseeable future. Our *Medical Marijuana Regulatory System, Part I Performance Audit* (March 2013) report addressed Revenue's licensing and regulation of medical marijuana businesses. This report focuses on our findings and recommendations related to Public Health's role in Colorado's medical marijuana regulatory system, including activities that affect medical marijuana patients, physicians, and primary caregivers.

Patient Access to Medical Marijuana

To buy, possess, and use medical marijuana in Colorado, a patient must meet certain eligibility requirements. For example, a patient must be a Colorado resident, and a physician must confirm that the patient suffers from one of the specific debilitating medical conditions that qualify an individual to use medical marijuana [Colorado Const., art. XVIII, sec. 14(3)(b)]. As discussed, statute [Section 25-1.5-106(5), C.R.S.] requires a patient to obtain a recommendation for medical marijuana from a physician "in good standing" with the State and with whom the patient has a bona fide relationship, as defined in statute.

Qualified patients must apply for a red card from Public Health. Patients who plan to obtain their medical marijuana from a dispensary or caregiver—rather than growing and cultivating it themselves—must provide information about their designated provider on their red card application. Red cards contain a unique serial number; the patient's name, address, date of birth, and social security number; the card issuance and expiration dates; and the name and address of the patient's provider, if one was designated at the time of application. A red card, which must be renewed annually, signifies that a patient is authorized to engage in the medical use of marijuana. Whenever patients possess any form of medical marijuana, statute [Section 25-1.5-106(9), C.R.S.] requires them to carry their red cards so they can demonstrate to law enforcement officers, upon request, that they are not violating the law. The following diagram summarizes the red card application and issuance process.

Red Card Application and Issuance Process



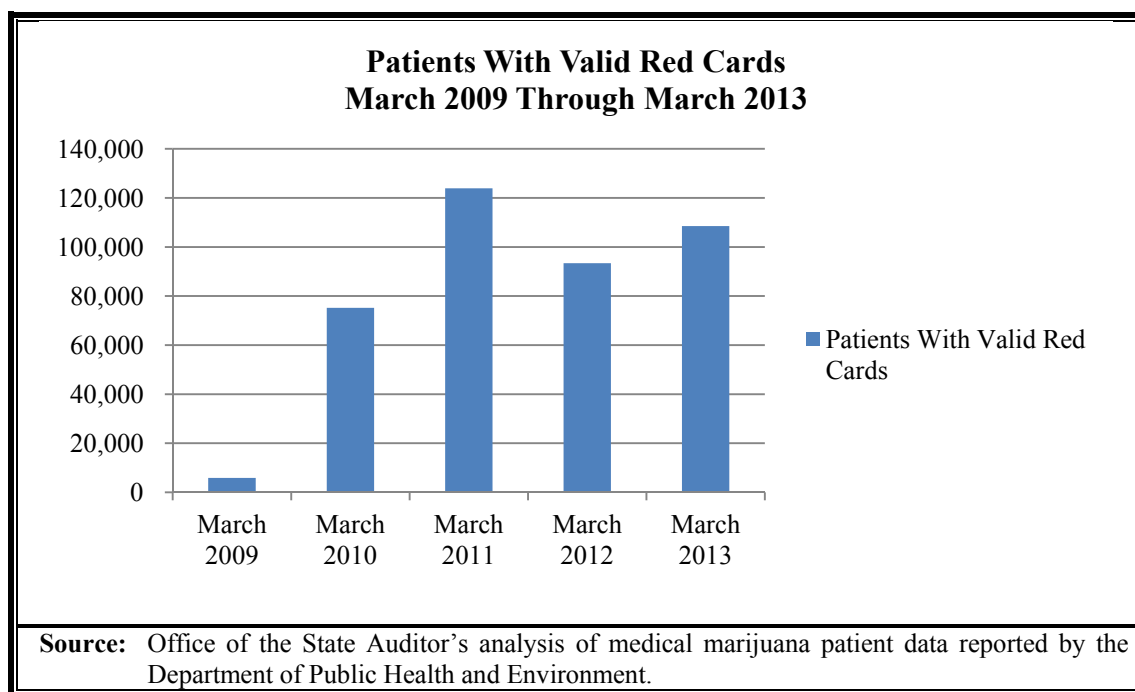
Source: Office of the State Auditor's analysis of information provided by the Department of Public Health and Environment; Article XVIII, Section 14 of the Colorado Constitution; and Section 25-1.5-106, et seq., C.R.S.

As of March 2013, about 108,000 patients in Colorado had valid red cards. According to data reported by Public Health, the following characteristics applied to these medical marijuana patients:

- Sixty-eight percent were male.
- The average age of all patients was 41 years.
- Thirty-five patients were minors (i.e., under the age of 18 years).
- Severe pain accounted for 94 percent of patients' reported medical conditions. The second-most reported medical condition was muscle spasms (16 percent of patients). Patients can report multiple conditions when applying for a red card.

- Fifty-eight percent of patients resided in the Denver metropolitan area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson Counties). The remaining patients resided in counties throughout Colorado.

Over the past 5 years, the number of patients who possess valid red cards has increased significantly. In March 2009, about 6,000 patients possessed valid red cards. By March 2013, that number had increased by 1,700 percent to about 108,000 patients. According to Public Health, one reason for the dramatic increase in red card applications after 2009 was the federal government's issuance of the Ogden memo, which indicated that federal drug enforcement resources would not focus on individuals using marijuana for medicinal purposes. The following chart shows a year-over-year comparison of the number of patients with valid red cards from March 2009 through March 2013.



The Colorado Constitution [art. XVIII, sec. 14(4)] allows patients to possess up to 2 ounces of useable marijuana and up to six marijuana plants at any given time. However, physicians can recommend quantities in excess of these amounts if doing so is medically necessary to address the patient's debilitating medical condition. Patients can obtain medical marijuana by (1) growing and cultivating marijuana plants for their personal medical use, (2) acquiring medical marijuana from their designated caregiver, or (3) purchasing medical marijuana from a dispensary. As noted previously, we discussed the role of medical marijuana businesses in our *Medical Marijuana Regulatory System, Part I Performance Audit* (March 2013) report. Therefore, the following section focuses only on the role of caregivers in providing medical marijuana and other services to patients.

Caregivers

The Colorado Constitution [art. XVIII, sec. 14(1)(f)] defines a “primary caregiver” as “a person, other than the patient and the patient’s physician, who is eighteen years of age or older and has significant responsibility for managing the well-being of a patient who has a debilitating medical condition.” State regulations further specify that in addition to growing and cultivating medical marijuana on behalf of patients, caregivers’ responsibilities should include assisting patients with daily living activities, such as transportation, housekeeping, or meal preparation.

Caregivers can legally operate throughout the state, even within local jurisdictions that have exercised their authority under Section 12-43.3-106, C.R.S., to prohibit medical marijuana businesses. Patients who wish to designate a caregiver must provide that individual’s name, address, and date of birth on their red card application and submit a copy of the designated caregiver’s photo identification to Public Health. A patient who designates a caregiver cannot also purchase medical marijuana from a dispensary, unless the patient is homebound and has obtained Public Health’s approval for his or her designated caregiver to purchase and transport medical marijuana from a dispensary on the patient’s behalf [Sections 25-1.5-106(8)(f), C.R.S., and 25-1.5-106(9)(e), C.R.S.].

Caregivers can serve up to five patients at any given time, although statute [Section 25-1.5-106(8), C.R.S.] grants Public Health the authority to allow caregivers to serve additional patients in exceptional circumstances. According to Public Health data we analyzed, as of December 2012 nearly 5,400 caregivers were serving about 8,500 medical marijuana patients. The following table provides a breakdown of how many caregivers were serving specified numbers of patients as of December 2012.

Caregivers Serving Medical Marijuana Patients As of December 2012		
Number of Patients	Number of Caregivers Serving Designated Number of Patients	Percentage of Total
More Than Five patients	52	1%
Five patients	95	2
Four patients	226	4
Three patients	439	8
Two patients	793	15
One patient	3,769	70
Total	5,374	100%
Source: Office of the State Auditor’s analysis of data provided by the Department of Public Health and Environment.		

Fiscal Overview

Funding for Public Health comes primarily from red card application fees. Patients pay the \$35 fee when they apply for a red card and then again each time they apply to renew their cards. All the revenue Public Health collects is deposited into the Medical Marijuana Cash Fund, which was established by House Bill 01-1371. Starting in Fiscal Year 2010, Public Health began to collect significantly higher revenue as the number of red card applications increased. In Fiscal Year 2010, Public Health received \$4.7 million in revenue, a 496 percent increase from the \$783,000 it collected in Fiscal Year 2009. By the end of Fiscal Year 2012, Public Health had a fund balance of \$12 million in the Medical Marijuana Cash Fund. The following table shows Public Health's medical marijuana-related revenue and expenses from Fiscal Years 2009 through 2012.

Medical Marijuana Cash Fund Department of Public Health and Environment Fiscal Years 2009 Through 2012				
	2009	2010	2011	2012
Beginning Balance	\$207,000	\$ 301,000	\$3,922,000	\$ 8,250,000
Revenue	783,000	4,670,000	9,848,000	6,414,000
Expenses	430,000	1,049,000	2,515,000	2,630,000
Cash Transfers	259,000 ¹	-	3,005,000 ²	-
Year-End Balance	\$301,000	\$3,922,000	\$8,250,000	\$12,034,000
Source: Office of the State Auditor's analysis of data from the Colorado Financial Reporting System. ¹ Senate Bill 09-208 authorized a \$259,000 transfer from the Medical Marijuana Cash Fund to the General Fund. ² House Bill 10-1388 authorized a \$3 million transfer from the Medical Marijuana Cash Fund to the General Fund. In addition, through Senate Bill 10-109 the General Assembly authorized Public Health to transfer monies from the Medical Marijuana Cash Fund for the investigation and prosecution of physicians referred to the Colorado Medical Board within the Department of Regulatory Agencies. During Fiscal Year 2011, Public Health transferred \$5,000 for this purpose.				

In Fiscal Year 2013, Public Health was appropriated \$2.1 million and 38.8 full-time-equivalent (FTE) staff to operate its medical marijuana program. In prior fiscal years, medical marijuana funds were rolled into the appropriation for the Health Statistics and Vital Records division and not reported separately. As of February 2013, Public Health employed 33 FTE who supported units involved with processing red card applications, issuing red cards, communicating with stakeholders, and addressing fraud risks.

Audit Purpose, Scope, and Methodology

We conducted this performance audit pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government. Audit work was performed from August 2012 through June 2013. This report is the second of two audit reports we issued with findings and recommendations related to Colorado's medical marijuana regulatory system. The first report, issued in March 2013, focused primarily on the business licensing and regulatory activities of the Medical Marijuana Enforcement Division, within Revenue. This report focuses primarily on Public Health's role in the State's medical marijuana regulatory system. We acknowledge the cooperation and assistance provided by staff at Public Health and Revenue.

The primary objective of this report was to assess Public Health's management of the process for issuing red cards giving individuals access to medical marijuana and its regulation of caregivers. Specifically, we evaluated:

- The confidentiality, security, and integrity of medical marijuana patient, caregiver, and physician data contained in the Registry.
- The efficiency of Public Health's red card issuance process and whether Public Health issues red cards only to eligible patients.
- The adequacy of Public Health's oversight of physician recommendations for medical marijuana and of caregivers.
- The adequacy of Public Health's efforts to monitor data related to physicians to identify potential concerns.
- Public Health's fee-setting and financial management practices.

We assessed the effectiveness of those internal controls that are significant to the audit objectives described above. Our conclusions on the effectiveness of those controls are described in the audit findings and recommendations.

To accomplish our audit objectives, we:

- Reviewed relevant federal and state laws, rules, regulations, policies, and procedures related to Public Health's red card application and issuance process, confidentiality of the Registry, and Public Health's oversight of physician recommendations for medical marijuana and of caregivers.

- Interviewed management and staff at Public Health and reviewed documentation to determine and assess Public Health's processes to issue red cards, oversee physician recommendations for medical marijuana, respond to requests for confidential Registry data, and oversee caregivers.
- Reviewed and analyzed contracts and other documentation to identify entities with past or present access to Registry data and evaluated the appropriateness of that access.
- Reviewed and analyzed non-personally-identifiable Registry data related to patients and caregivers to identify trends or potential areas of concern.
- Reviewed and analyzed documentation related to Registry confidentiality breaches that occurred from January 2009 through December 2012.
- Reviewed and analyzed data and budget documentation related to program funding and red card application fee rates to assess the sufficiency of Public Health's fee-setting practices.
- Reviewed and analyzed payment data to assess Public Health's processes and procedures for authorizing and justifying expenses.
- Interviewed industry stakeholders around the state, including four law enforcement agencies, four local governments, and six medical marijuana businesses.
- Reviewed basic medical marijuana program information from 18 states and the District of Columbia, all of which have passed state laws legalizing the use of marijuana for medical purposes.

We relied on sampling techniques to support our audit work as follows:

- We selected a nonstatistical judgmental sample of 30 Public Health expenses from Fiscal Years 2011 and 2012. The sampled expenses included a range of low- to high-dollar amounts and totaled about \$210,000. We designed our sample to provide sufficient, appropriate evidence for our evaluation of Public Health's financial management practices.
- We selected a nonstatistical random sample of 10 contract employees with access to the Registry as of October 2012 to determine whether those individuals had signed a confidentiality agreement. We designed our sample to provide sufficient, appropriate evidence for our evaluation of Public Health's process for obtaining signed confidentiality statements.

The results of our sample testing were not intended to be projected to the entire population. Rather, sampled items were selected to provide sufficient coverage of areas that were significant to the objectives of this audit. Specific details about the audit work supporting our findings, conclusions, and recommendations are described in the remainder of the report.

Scope Limitation

Our ability to analyze Public Health data was limited by a constitutional provision that restricts access to patient, caregiver, and physician data contained in the Registry. Specifically, Article XVIII, Section 14(3)(a) of the Colorado Constitution allows only “authorized employees” of Public Health and law enforcement agencies, under certain circumstances, to access Registry information. We sought legal guidance from the Office of Legislative Legal Services and the Office of the Attorney General to determine whether the State Auditor’s authority to access state records under Section 2-3-107(2), C.R.S., would allow us to obtain and analyze Registry data. In general, our legal counsel concluded that we did not have authority to access Registry data. However, the Office of the Attorney General advised that we could access generic Registry data as long as it did not reveal anything confidential about specific medical marijuana patients, caregivers, or physicians. To the extent that it helped us fulfill our audit objectives, we analyzed generic Registry data that Public Health provided.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Access Controls

Chapter 2

As discussed in the Overview, individuals apply to the Department of Public Health and Environment (Public Health) to obtain a “red card” that will allow them to access medical marijuana. The main qualifications for a red card are that the applicant be a Colorado resident and suffer from a debilitating condition that would, in the opinion of a physician, benefit from treatment with medical marijuana. As a result, the application materials must include a certification from a physician that the individual suffers from one of the debilitating medical conditions (e.g., cancer or severe pain) that qualify one to use medical marijuana and a recommendation from the physician for the amount of medical marijuana that would be beneficial to the patient. Public Health staff review the application and issue the red card if the individual meets all of the qualifications.

It is important that Public Health have effective controls over the access to medical marijuana because of the strong incentives that have existed for obtaining a red card inappropriately. For example, individuals without debilitating medical conditions could want to obtain a red card because it would allow them to use marijuana without fear of prosecution under the State’s criminal laws related to marijuana (Colorado Const., art. XVIII, sec. 14). Although marijuana use remains illegal under federal law even for medical marijuana patients, federal law enforcement officials have specifically stated, as discussed in the Overview, that prosecuting individuals who are in compliance with state medical marijuana laws will not be a priority of the federal government. As a result, individuals without a debilitating medical condition who use or would like to use marijuana would be motivated to obtain a red card to significantly reduce their risk of being prosecuted for using marijuana in Colorado. In addition, individuals may have an incentive to obtain recommendations from their physicians for more than the standard six marijuana plants and 2 ounces of useable marijuana normally allowed for by the Constitution if they planned on distributing the excess marijuana to individuals without red cards (which would be illegal).

As also discussed in the Overview, the passage of Amendment 64 legalizes the recreational use of marijuana for all adults 21 years of age or older in Colorado. This amendment may jeopardize the long-term viability of the medical marijuana industry and reduce or eliminate the incentives for individuals to inappropriately obtain a red card or a higher-than-normal recommended amount of marijuana. However, this is not certain because (1) it is unknown how the federal government will respond to the passage of Amendment 64; (2) higher taxes on recreational marijuana, if approved by the voters, may encourage individuals

without a debilitating medical condition to continue seeking a red card to obtain marijuana more cheaply; and (3) individuals under the age of 21 would still have an incentive to obtain a red card inappropriately if they want to use marijuana but do not have a debilitating medical condition.

We tested the controls Public Health has in place to ensure that only qualified individuals have received red cards with appropriate recommendations for the amount of marijuana needed. Restrictions established by the Colorado Constitution on the release of information from Public Health's Medical Marijuana Registry (the Registry) related to patients, physicians, and caregivers limited the types of analysis that we could perform in this area. Specifically, while we were able to test the design of Public Health's controls to ensure that only qualified individuals receive red cards, we could not directly test whether the controls were working properly. For example, we evaluated whether the red card application is designed to collect all required information, but we could not review actual red card applications received by Public Health to confirm that the approved applications had met all applicable requirements. However, we were able to indirectly test whether Public Health's controls were working properly by analyzing aggregate data from the Registry.

Overall, we found that Public Health's controls over access to medical marijuana do not provide reasonable assurance that only qualified individuals are receiving red cards. Specifically, Public Health does not have sufficient oversight of physicians to ensure they are making appropriate recommendations for marijuana. In addition, we found that Public Health has experienced problems processing red cards within the deadline established by the Constitution. We also found that Public Health's controls for monitoring which dispensaries and caregivers patients designate as their providers are not strong. Finally, we found that Public Health's oversight of caregivers in general could allow individuals to circumvent controls designed to ensure that medical marijuana is not diverted outside the industry. We discuss our findings related to physician recommendations, timeliness, provider affiliation, and caregivers in the four sections of this chapter.

Physician Oversight

Ideally, only individuals with legitimate, qualifying debilitating medical conditions would receive a red card and be placed on the Registry. Physicians and the oversight of their actions are the main controls for ensuring that nonqualifying individuals do not gain access to medical marijuana. Specifically, as part of issuing a red card, Public Health staff rely on physicians making appropriate recommendations for applicants to use medical marijuana.

The Colorado Constitution, statute, and regulations lay out a number of requirements for ensuring that physicians appropriately recommend the medical use of marijuana for their patients. Under these requirements, physicians must:

- Have a valid, unrestricted license to practice medicine in Colorado that does not prohibit the physician from recommending medical marijuana.
- Comply with generally accepted standards of medical practice, the provisions of the Colorado Medical Practice Act (Section 12-36-101, et seq., C.R.S.), and all Colorado Medical Board (Medical Board) rules.
- Have a valid and unrestricted U.S. Department of Justice federal Drug Enforcement Administration controlled substances registration (DEA registration), which is designed to prevent illegal prescription activity.
- Have a bona fide physician–patient relationship with the applicant, meaning that (1) the physician and a patient have a treatment or counseling relationship, during which the physician has completed a full assessment of the patient’s medical history and current medical condition, including an appropriate personal physical examination; (2) the physician has consulted with the patient with respect to the patient’s debilitating medical condition before the patient applies for a red card; and (3) the physician is available to or offers to provide follow-up care and treatment to the patient, to determine the efficacy of the use of medical marijuana as a treatment of the patient’s debilitating medical condition.
- Make a determination and certify to Public Health that the patient has a debilitating medical condition and that the patient may benefit from the use of medical marijuana.
- Specify for Public Health the patient’s chronic or debilitating disease and, if known, the cause or source of the chronic or debilitating disease or medical condition.
- Maintain a recordkeeping system for all patients for whom the physician has recommended the medical use of marijuana and make those records available to the Medical Board pursuant to an investigation.

In addition to the requirements above, statute [Section 25-1.5-106(5)(d), C.R.S.] prohibits physicians who recommend medical marijuana for their patients from being connected with a medical marijuana provider. Specifically, physicians are prohibited from (1) accepting, soliciting, or offering any form of monetary payment from any provider of medical marijuana; (2) offering a discount or any other thing of value to a patient who uses or agrees to use a particular provider of

medical marijuana; (3) examining a patient at a location where medical marijuana is sold or distributed; or (4) holding an economic interest in any medical marijuana business.

Public Health oversees physician recommendations by requiring individuals to submit a physician certification with their applications to receive a red card. On the certification form, the physician indicates the patient's qualifying medical condition and whether the patient needs the standard or an increased amount of marijuana and signs a statement attesting that the physician has a bona fide relationship with the patient and that the patient may benefit from the medical use of marijuana. Once Public Health receives the application, it independently verifies that the physician has an unrestricted medical license and DEA registration. Public Health also attempts to verify that physicians have made legitimate patient recommendations by sending out letters to physicians asking them for confirmation of their signatures on the physician certification form.

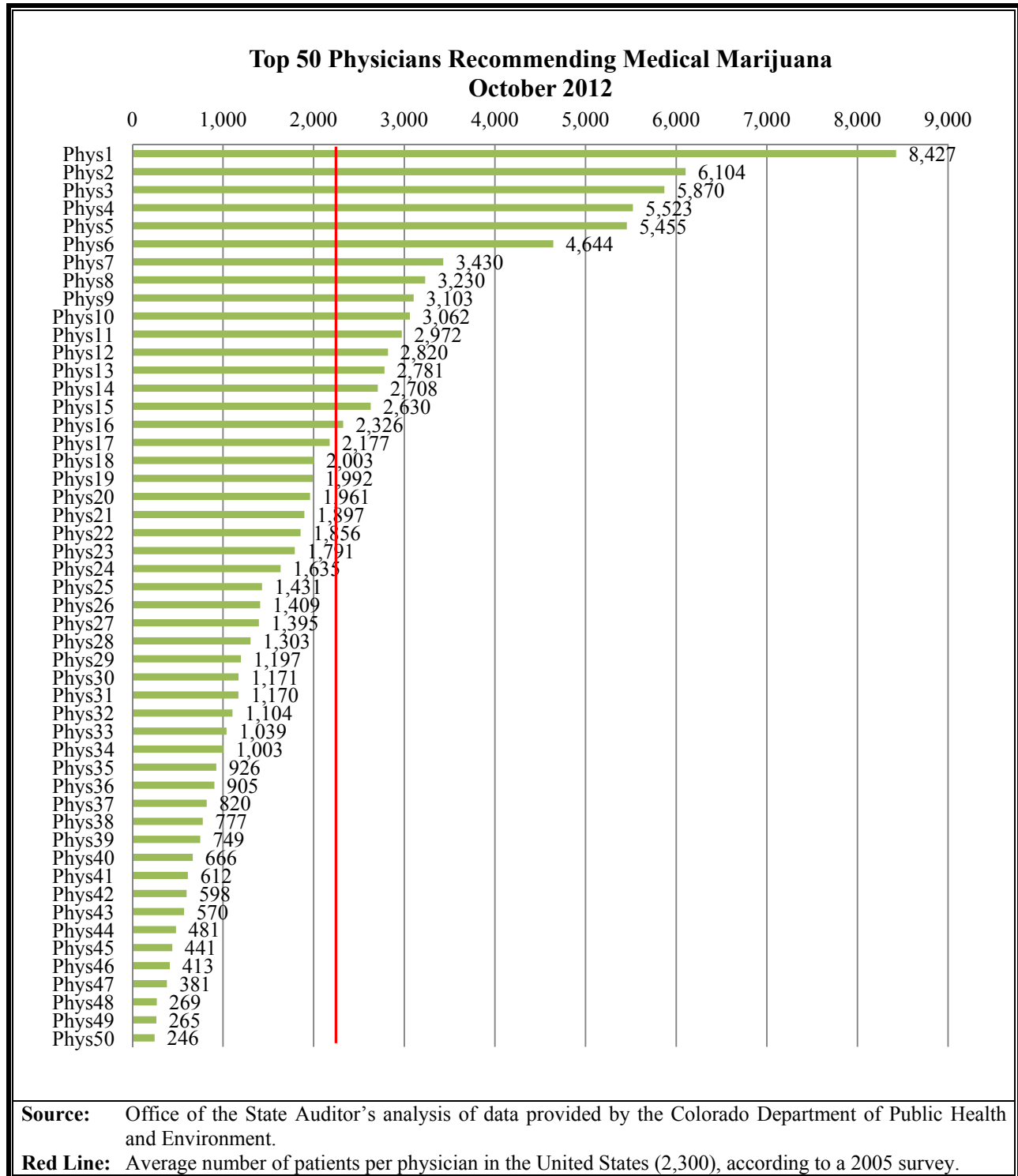
We evaluated the effectiveness of Public Health's oversight of physician recommendations by reviewing the physician certification form and analyzing aggregate, non-personally-identifiable data from Public Health showing the number of Registry patients per physician. We also reviewed studies published about physician characteristics and attitudes relevant to the medical marijuana industry and conducted research on physicians advertising medical marijuana-related services in Colorado. We did not review completed physician certification forms or other application materials submitted by individuals because of the aforementioned prohibitions in the Colorado Constitution.

Overall, we found evidence suggesting that some physicians are making inappropriate recommendations for medical marijuana or have improper relationships with medical marijuana businesses and are, therefore, helping nonqualifying individuals to gain access to medical marijuana. Specific problems we identified included (1) a small number of physicians making the majority of the patient recommendations for medical marijuana, (2) suspicious advertising by physicians, (3) the prevalence of severe pain as the qualifying debilitating medical condition for Registry patients, (4) recommendations for extremely high plant counts, and (5) studies providing anecdotal data on inappropriate physician recommendations. We discuss each of these issues below.

Number of recommendations per physician. We found that a majority of patients on the Registry were recommended by a small group of physicians who have more medical marijuana patients than appears reasonable. It is not clear exactly how many patients per physician would be too many to allow for a bona fide physician-patient relationship in each case for the purposes of recommending marijuana for medical use. Public Health has not established such criteria. However, a 2005 survey of national physician, patient, and practice characteristics

published in the *Journal of General Internal Medicine* found that U.S. physicians have an average of 2,300 patients each.

Using this average physician patient load as a benchmark, we analyzed data provided by Public Health to determine how many physicians recommended more than 2,300 patients for the Registry. As of October 2012, a total of 903 physicians had recommended medical marijuana for the roughly 108,000 patients holding valid red cards. Because red cards are valid for 1 year, each of these recommendations would have been made in the year prior to October 2012. We found that 60 percent of these recommendations came from 16 physicians. These 16 physicians had recommended medical marijuana in the preceding year to more patients than the average U.S. physician annual caseload of 2,300 patients. One physician had more than 8,400 recommendations. Further, the 12 (1 percent) physicians with the most medical marijuana recommendations recommended marijuana for 50 percent of the patients on the Registry. The chart below shows the 50 physicians with the most medical marijuana recommendations.



Because of the age of the study, the 2,300-patient benchmark may not be the best threshold for determining when physicians are making too many medical marijuana recommendations for the recommendations to have likely been based on a legitimate examination of the patient's medical condition. However, the analysis above still suggests that some physicians may not have had a bona fide relationship with all the individuals for whom they recommend medical marijuana.

Public Health has had concerns regarding physicians who recommend medical marijuana for large numbers of patients. In January 2011, Public Health identified five physicians as possibly making inappropriate recommendations for medical marijuana and referred those physicians to the Medical Board for investigation. In those cases, the five physicians had each recommended medical marijuana for more than 1,200 individuals in the previous 7-month period and were collectively responsible for more than 22 percent of all recommendations over that period. As a result of Public Health's referrals, the Medical Board found there was reasonable cause to believe that violations of the Medical Practice Act had occurred in four of the five cases that warranted further investigation by the Medical Board. Public Health reported that in one of the four cases, the physician's license was suspended and in another case, there was a "letter of agreement" with the physician that, among other provisions, prohibited the physician from making further medical marijuana recommendations. For the remaining three of the five cases referred to the Medical Board, Public Health reported knowing that all three physicians are still in good standing with the Medical Board but not whether the Medical Board had completed its investigations of these three physicians.

Physician advertising. We conducted a basic Internet search and identified 12 websites for Colorado physicians advertising their services for performing evaluations that could result in a recommendation to use medical marijuana. Claims made by these physicians' websites indicated that not all of these medical evaluations would be genuine or objective, as described below.

- **Convenience for easy access to marijuana.** All websites we reviewed made claims about the convenient services they provide for getting access to medical marijuana. For example, a number of websites advertised same-day service, where patients can leave the physician's office with all the paperwork they need to be able to purchase marijuana, and other websites advertised night and weekend hours and the availability of walk-in assistance. The claims of convenience for gaining easy access to marijuana suggest that these physicians may not be primarily interested in providing an objective evaluation of the patient's medical condition. For example, one website claimed: "Our company's core business is getting patients registered with the state medical marijuana program by referring

patients to intelligent and open minded doctors specializing in medical marijuana.”

- **High plant counts.** Three websites we reviewed advertised the availability of getting a recommendation for a higher-than-standard marijuana plant count. In two cases, the website indicated that a higher plant count was available for an additional fee. The third website advertised that it had “highest edible counts,” a reference to the physicians being willing to recommend the higher plant counts that are required to produce edible (i.e., food- and drink-based) marijuana products. While the Constitution allows for higher-than-standard plant counts when “medically necessary to address the patient’s medical condition” [art. XVIII, sec. 14(4)(b)], physicians with websites stating that they would be willing to recommend higher plant counts may not be determining the medical necessity for those higher plant counts.
- **Medical records not necessary.** Five websites we reviewed indicated that medical records were not necessary for the medical marijuana evaluation. For example, one website claimed: “No prior medical records are necessary. Our doctors are qualified to provide you with the original diagnosis with or without medical history. If you don’t have medical history, that is not a problem.” Section 25-1.5-106(2)(a), C.R.S., which defines a bona fide physician–patient relationship, specifies that the physician must complete a full assessment of the patient’s medical history and current medical condition before the patient applies for a red card. Physicians who advertise that individuals do not need to bring medical records may not be completing a full assessment of the individual’s medical history before recommending medical marijuana for the individual.
- **Refunds and guarantees.** One website advertised the availability of a refund of all the processing fees and half of the medical evaluation fee if the physician finds the patient does not have a qualifying medical condition. Another website guaranteed that the paperwork would be accepted by Public Health. Physicians who guarantee such results may not be conducting objective evaluations of the individual’s medical condition.
- **On-site physicians and possible financial ties with dispensaries.** Three websites advertised the availability of on-site physicians where medical marijuana is sold. Section 25-1.5-106(5)(d)(III), C.R.S., prohibits physicians from examining a patient for the purposes of diagnosing a debilitating medical condition at a location where medical marijuana is sold or distributed. We also found three websites that offered discounts or incentives for using certain dispensaries. As previously stated, Section 25-

1.5-106(5)(d), C.R.S., prohibits physicians from soliciting or offering any form of monetary payment from or to a medical marijuana provider, or offering a discount or any other thing of value to a patient who uses or agrees to use a particular medical marijuana provider.

Because we could not access personally identifiable Registry data, we could not conduct further audit work to determine the extent to which any of the physicians we found to be advertising had made recommendations for patients currently on the Registry.

Percentage of patients reporting severe pain. Data released monthly by Public Health shows that the percentage of individuals on the Registry reporting severe pain as their only qualifying condition has increased sharply in recent years. Specifically, the table below shows that the percentage of patients claiming severe pain as a qualifying condition increased from 87 percent in January 2009 to 94 percent in January 2013. At the same time, the percentage of all other qualifying medical conditions claimed by patients decreased. As a result, these data show that in January 2009 at least 30 percent of Registry patients reported severe pain as their only qualifying medical condition (87 percent with severe pain minus the 57 percent with all other qualifying medical conditions), whereas in January 2013, at least 59 percent of Registry patients reported severe pain as their only qualifying medical condition (94 percent with severe pain minus the 35 percent with all other qualifying medical conditions).

Medical Conditions of Medical Marijuana Registry Patients As Reported by Patient's Physician¹ January 2009 To January 2013					
Medical Condition	January 2009		January 2013		Increase/ Decrease in Percentage 2009-2013
	Number of Patients	Percentage	Number of Patients	Percentage	
Cachexia	99	2%	1,253	1%	↓
Cancer	190	4	2,886	3	↓
Glaucoma	75	2	1,088	1	↓
HIV/AIDS	93	2	688	1	↓
Muscle Spasms	1,098	22	17,596	16	↓
Seizures	206	4	1,838	2	↓
Severe Pain	4,388	87	101,751	94	↑
Severe Nausea	1,068	21	11,764	11	↓
Total Patients	5,051	-	108,656	-	-
Source: Office of the State Auditor's analysis of data provided by Colorado Department of Public Health and Environment.					
¹ Physicians may indicate more than one medical condition for a patient. Therefore, number of patients do not equal total at the bottom of the table, and percentages add up to more than 100 percent.					

The high percentage of patients reporting severe pain as a qualifying medical condition has raised concerns about the diagnosis. For example, staff reported that in 2010 when the percentage of patients reporting severe pain as a qualifying condition crossed the 90 percent threshold, they received a legislative inquiry. As a result, they added a question to the physician certification form asking physicians to identify the cause or source of the severe pain, if known.

It is important to note that because we could not access personally identifiable information from the Registry, we were unable to analyze trends in medical conditions reported by patients, such as whether patients reporting only severe pain were more likely to have been referred by a physician with a higher than reasonable patient count or one that includes questionable claims in his or her advertising.

Extremely high plant counts. We analyzed a subset of data provided by Public Health showing aggregated data for patients with caregivers and found evidence that some patients have had what appear to be higher than reasonable plant counts recommended for them by their physicians. For example, in one case, the physician had recommended 501 plants for the patient, and in another case, the physician had recommended 75 ounces of useable marijuana for the patient. Although an increased plant and ounce count over the standard six plants and 2 ounces may be appropriate for a patient who is consuming marijuana through edibles or tinctures (as opposed to smoking), a dispensary owner we spoke to during the audit reported that no patient should need more than 25 plants to make his or her edible or tincture products. We also heard anecdotal evidence from law enforcement officials and the dispensary owner about physicians who routinely mark patients down for increased plant and ounce counts, regardless of the patient's need for an increased count.

Anecdotal data. We identified two studies with anecdotal evidence suggesting that not all patients on the Registry have a legitimate, qualifying medical condition. For example, a 2013 study of Colorado family physicians published in *The Journal of the American Board of Family Medicine* reported that a significant number of physicians surveyed believe that medical marijuana is being used predominantly by people who are well but want legal protection for recreational marijuana use. The study also found that the physicians in the study who had recommended medical marijuana for their patients reported severe pain as a qualifying condition in 76 percent of cases, compared to the 87 to 94 percent reported in the Registry population overall. These results led the researchers to conclude, "The gulf between physicians who are providing medical marijuana recommendations as a substantial portion of their practice and primary care providers who are far more likely to have a continuity relationship with a patient suggests that a continuity relationship influences provider behavior related to medical marijuana and may lead to a more judicious recommendation of medical marijuana."

Law enforcement officials we spoke to during the audit echoed the concern about healthy individuals using the Registry as legal protection for recreational marijuana use, and a study released in August 2012 by the Rocky Mountain region of the federal High Intensity Drug Trafficking Area Program, which works to coordinate drug-control efforts among local, state, and federal law enforcement, identified specific incidents in which marijuana from Colorado's medical marijuana industry appeared to have been diverted by patients, caregivers, and dispensaries to the black market for recreational purposes.

Improving Physician Oversight

The issues discussed above provide substantial evidence suggesting that not all medical marijuana recommendations made by physicians are legitimate. The risk that nonqualifying individuals are gaining access to the Registry exists because the controls Public Health has in place for overseeing physician recommendations for medical marijuana are not effectively designed to prevent illegitimate physician recommendations and because Public Health has not implemented additional controls that would provide greater assurance that all physician recommendations are genuine. We discuss both of these issues below.

Ineffectively designed controls. As discussed, Public Health relies on the physician's certification form and the verification of physicians' signatures as controls to ensure the validity of physician recommendations. However, these controls are not designed effectively to ensure the appropriateness of physician recommendations, as discussed below.

- **Physician certification form.** We found that the physician certification form does not collect all information required by statute. The current form asks for the patient's qualifying medical condition, the dosing amount (i.e., the standard or an increased amount of marijuana), and a certification stating that the physician has a bona fide relationship with the patient and that the patient may benefit from the medical use of marijuana. However, the form does not ask for (1) the cause or source of the patient's qualifying medical condition, unless severe pain is the qualifying condition; (2) the reason (if applicable) that amounts of marijuana larger than the standard six plants and 2 ounces are medically necessary; and (3) confirmation that the physician understands that he or she cannot have financial ties to medical marijuana businesses. These elements missing from the physician certification form leave Public Health without key information that would provide greater assurance that physicians are making appropriate medical marijuana recommendations.
- **Physician confirmation letters.** We found that Public Health's process for confirming physician signatures on the certification form adds little

value to Public Health's efforts to ensure appropriate recommendations for medical marijuana. Specifically, patients send the physician certification form with their applications rather than having physicians provide the form directly to Public Health. As a result, there is a risk that a physician certification could be forged by an applicant. To mitigate this risk, Public Health sends periodic patient lists to all physicians asking them to confirm that they recommended medical marijuana for all patients on the list. Public Health's confirmation process is "negative," meaning that physicians are asked to contact Public Health only if there are patients on the list that the physician did *not* recommend. Conversely, a "positive" confirmation process would require physicians to affirm in writing to Public Health that he or she recommended medical marijuana for each patient on the list.

Negative confirmation processes generally provide less assurance than positive confirmations because the lack of a reply is interpreted as a satisfactory reply (i.e., the physician agrees that he or she has recommended all the patients on the list sent by Public Health), even though the physician may have actually ignored the confirmation request. Negative confirmations also generally result in lower response rates. Public Health's experience is consistent with this assumption. Specifically, we reviewed Calendar Year 2012 data and found that Public Health received only one response, out of more than 2,200 letters sent in 2012, from a physician stating that he or she had not recommended medical marijuana for a particular patient. In this case, the physician subsequently reviewed the certification that Public Health had on file for the patient and confirmed that he had indeed completed the paperwork for the patient but had not kept a copy for his records.

Because of its limitations, negative confirmation processes are generally reserved for situations when the risk of noncompliance is low. As we have discussed, the risk that individuals would try to obtain a red card inappropriately has been, and may remain, significant. Therefore, using a positive confirmation process on a risk basis (e.g., targeting confirmation to the physicians with the highest number of recommendations) would provide greater assurance that physicians are actually making the recommendations claimed on red card applications while also being more efficient and cost-effective than negative confirmations.

Additional controls available. Public Health staff stated that their ability to oversee physician recommendations for medical marijuana is limited because they do not have the expertise or the authority to determine that a physician has made an error, or otherwise acted inappropriately, in recommending medical marijuana for a patient. Staff further indicated that the Medical Board is the more suitable regulatory body for making these types of determinations.

We acknowledge that Public Health is not the proper entity for reviewing the quality of a physician's clinical decisions. Even so, Public Health has not implemented additional controls over the physician recommendation process that are within its expertise and authority, as discussed below.

- **Monitoring data.** Public Health does not routinely monitor data or conduct research to identify high-risk physicians. Public Health periodically provides physician data to the Board of Health and legislators, as requested, but does not currently track physician recommendation statistics or trends on a regular basis or conduct other research to monitor physicians. For example, Public Health provided us with two reports that were run to show the number of patients per physician; one report was run in May 2011 and one was run in October 2012. However, these patients-per-physician reports are not run regularly and are not analyzed by staff to identify physicians who may be making inappropriate recommendations. Additionally, Public Health staff do not run other types of reports on data they currently collect that could be helpful in indicating high-risk physicians, such as:
 - Physicians who recommend more than the standard amounts of marijuana.
 - Physicians who report severe pain as the only qualifying medical condition for a higher-than-average number of their patients.
 - Physicians with a higher-than-average number of young patients, including physicians who recommend marijuana for minors.
 - Physicians located in a different city than the patients for whom they recommended marijuana, which could indicate that the physician did not conduct an in-person examination.

In addition, Public Health staff do not conduct research on physicians, such as performing Internet searches of physicians advertising their services for providing medical marijuana evaluations or comparing physicians' addresses with the addresses of dispensaries.

- **Enforcement actions.** Public Health has two main enforcement actions it can use against physicians. First, statute [Section 25-1.5-106(6)(a), C.R.S.] allows Public Health to refer physicians to the Medical Board for investigation if Public Health has reasonable cause to believe that a physician has violated certain constitutional, statutory, or regulatory provisions related to recommending medical marijuana for patients. As discussed above, Public Health referred five physicians to the Medical Board in January 2011 for investigation of their medical marijuana recommendation practices. These referrals resulted from Senate Bill 10-109, which included language to clarify Public Health's authority to refer physicians to the Medical Board for investigation and to conduct its own

investigations of physicians. The legislation also provided for a 2-year window in which Public Health could reimburse the Medical Board for investigation of up to five physicians per year in Fiscal Years 2011 and 2012 in an effort to “weed out the bad actors,” as one legislator explained in the committee hearing. The five physicians referred by Public Health represented the five physicians who had made the most recommendations at that time. In addition to these five physicians, Public Health referred a sixth physician based on a complaint to the Medical Board for investigation in December 2010 for allegedly not conducting medical examinations in person. Public Health reported never receiving feedback from the Medical Board about this sixth case. Although Public Health still has the authority to refer physicians to the Medical Board for investigation, it has not made additional referrals. Public Health has also not developed criteria or other risk factors for determining which physicians to refer.

Second, statute [Section 25-1.5-106(6)(b), C.R.S.] authorizes Public Health to conduct a hearing if it has reasonable cause to believe upon a full investigation that a physician has violated any of the statutory prohibitions against physicians having financial ties with medical marijuana businesses. The purpose of the hearing is to determine whether a violation has occurred. As discussed above, Public Health does not proactively attempt to identify possible violations. It has also not conducted any hearings related to possible violations by physicians. Public Health staff expressed concern about being able to conduct a full investigation of a physician’s financial ties with medical marijuana businesses in part because it is not clear Public Health can compel a physician to provide records during an investigation. Section 25-1.5-106(5)(c), C.R.S., does specifically say that physicians shall provide records to the Medical Board pursuant to an investigation, but statute does not have a similar requirement for providing records to Public Health.

- **Dosing information.** Public Health does not currently have a mechanism to make information available to physicians about reasonable or excessive plant and ounce counts for patients. In 2012, Public Health amended the physician certification form to require that a physician specify whether he or she recommended the standard amount of six plants and 2 ounces or an increased plant and ounce count. Public Health staff reported that physicians expressed frustration with the change in the form because they did not know when they should recommend an increased plant and ounce count and what appropriate amounts would be. Physicians have controlled substance dosage guidance through the Physicians’ Desk Reference; however, this guide does not include medical marijuana. With 18 states and the District of Columbia legalizing medical marijuana, and more

considering it, the demand for information to help physicians determine appropriate dosages will increase. Public Health could create a repository on its website for evidence-based studies on medical marijuana dosing as that information becomes available.

Weak controls over physician recommendations increase the risk that patients without a qualifying medical need are put on the Registry and therefore can gain access to medical marijuana that they do not legitimately need. This is especially concerning for individuals under age 21 who, even with the passage of Amendment 64, are not entitled to purchase or possess marijuana of any kind without a physician recommendation. These weak controls also undermine the legitimacy of marijuana as a medical treatment by fostering the impression that physician recommendations for marijuana are not held, or should not be held, to the same rigorous standards as a typical prescription for medicine. As a result, it is in the interest of Public Health, physicians, and medical marijuana advocates to help ensure that physicians are only making legitimate recommendations for using medical marijuana.

Recommendation No. 1:

The Department of Public Health and Environment (Public Health) should improve its oversight of physician recommendations for medical marijuana by:

- a. Discontinuing its negative confirmation process for verifying physician recommendations and instead developing a risk-based approach for positively confirming physician recommendations periodically.
- b. Revising the physician certification form to require that physicians (i) complete the cause, if known, of the patient's qualifying medical condition; (ii) explain the reason why the physician is recommending increased marijuana above the standard counts (if applicable); and (iii) attest to not having financial ties with any medical marijuana business.
- c. Working with the Colorado Medical Board to determine risk factors that Public Health can use to identify potentially inappropriate physician recommendations and to establish guidelines for initiating investigation of physicians or making physician referrals to the Colorado Medical Board for further investigation.
- d. Establishing policies and procedures for routinely analyzing data from the Medical Marijuana Registry and conducting other research as appropriate to monitor to the risk factors and guidelines identified in part "c" and to

identify physicians who should be referred to the Colorado Medical Board for further investigation.

- e. Establishing policies and procedures for conducting research to identify physicians who should be investigated for having financial ties with medical marijuana businesses, conducting hearings pursuant to Section 25-1.5-106(6)(b), C.R.S., and seeking statutory change if more authority is needed for obtaining physicians' records pursuant to investigations.
- f. Creating a repository on its website for evidence-based studies and other information as it becomes available on appropriate dosing of marijuana for medical use.

Department of Public Health and Environment Response:

- a. Agree. Implementation date: December 2013.

The Department has discontinued its negative confirmation process. The Department will develop and implement a risk-based approach for positively confirming physician recommendations periodically.

- b. Agree. Implementation date: January 2014.

The Department will revise the physician certification form to require that physicians (i) complete the cause, if known, of the patient's qualifying medical condition; (ii) explain the reason why the physician is recommending increased marijuana above the standard counts; and (iii) attest to not having financial ties with any medical marijuana business.

- c. Agree. Implementation date: March 2014.

The Department will work with the Colorado Medical Board to determine risk factors that the Department can use to identify potentially inappropriate physician recommendations and to establish guidelines for initiating investigation of physicians and/or making physician referrals to the Colorado Medical Board for further investigation.

- d. Agree. Implementation date: March 2014.

The Department will establish policies and procedures for routinely analyzing data from the Medical Marijuana Registry and conducting other research, as appropriate, to monitor the risk factors and guidelines identified in part c of this Recommendation 1, and to identify physicians who should be referred to the Colorado Medical Board for further investigation.

- e. Partially agree. Implementation date: July 2014.

It is unclear if the Department has the legal authority to compel physicians making medical marijuana recommendations to provide access to their records for purposes of an investigation into their purported financial ties with medical marijuana providers. Additionally, the Department does not currently have the capacity to conduct investigations into physicians' financial ties to medical marijuana providers. However, the Department may seek legal advice on its authority to obtain records from physicians making medical marijuana recommendations, and will explore options to develop this physician financial investigation capacity. Based upon the advice received and the availability of resources, the Department will establish policies and procedures for conducting research to identify physicians who should be investigated for violations.

Auditor's Addendum:

As noted in the audit report, statute does not specifically grant Public Health access to physicians' records for purposes of an investigation. Our recommendation does not assume that such access exists, but focuses on Public Health conducting research to identify physicians who may have financial ties with medical marijuana businesses and taking appropriate action with respect to such physicians, as authorized in Section 25-1.5-106(6) C.R.S. The recommendation acknowledges that Public Health may need to seek additional statutory authority to fulfill its responsibilities for investigating physicians.

- f. Agree. Implementation date: July 2014.

Pursuant to Senate Bill 13-283, the Department is required to monitor "the emerging science and medical information relevant to the health effects associated with marijuana use," and further to

appoint a panel of health care professionals to review the information and create a report every 2 years starting in January 2015. The panel report is required to be posted on the Department's website. The Department will create a repository on this website for evidence-based studies as they become available on appropriate dosing of marijuana for medical use.

Timeliness of Application Processing

Amendment 20 put into place requirements that Public Health process red card applications within 35 days of receiving the patient's red card application [Colorado Const., art. XVIII, sec. 14(3)(c)]. Although provisions in the law allow for some patients to use a copy of their red card applications to access marijuana from a dispensary during the 35-day period during which Public Health has to process applications, these provisions do not extend beyond the 35-day period or apply to patients applying to renew their expired red cards [Section 12-43.3-402(5), C.R.S.]. Timely processing of applications is therefore important to ensure that patients have uninterrupted access to the medical marijuana that their physicians have recommended for them.

We tested the timeliness of Public Health's processing of red card applications to determine if Public Health is meeting the 35-day deadline established by the Colorado Constitution. To do this, we obtained an abstract of data from the Registry as of December 2012 showing key processing dates such as application receipt date and red card issue date. The data did not include any personally identifiable information about patients, caregivers, or physicians. It should be noted that it is Public Health's position that only new applications or renewal applications must be processed within 35 days. Other types of applications, such as a request for a replacement card because it was lost, stolen, or destroyed, do not have to be processed within 35 days, according to Public Health.

We found that Public Health failed to issue red cards within the constitutionally required 35-day time frame for more than one-third of red cards that were valid as of December 2012. Specifically, of the about 101,000 valid red cards in the dataset that were new or renewal cards, about 29,000 (29 percent) were issued in more than 35 days. In more than 900 cases (1 percent), it took more than 60 days to issue the red card.

Total Time to Issue Red Cards Valid as of December 20, 2012			
	Total Processing Days	Number of Red Cards	Percentage
	0-35	71,838	71%
Total Processed Within 35 Days		71,838	71%
	36-45	23,261	23
	46-60	5,052	5
	>60	923	1
Total Processed In More Than 35 Days		29,236	29%
	Unknown	134	<1
Total Unknown¹		134	<1%
Total²		101,208	100%
Source: Office of the State Auditor's analysis of data from the Medical Marijuana Registry as of December 20, 2012. ¹ We could not assess timeliness for the 134 records for which there was no recorded application receipt date or where the application receipt date was marked after the date of issue. ² This total figure differs from the 108,000 figure cited elsewhere in the report because our analysis excluded all records in which a patient had requested a replacement card. For replacement cards, limitations in the Registry's database controls prevented us from measuring the timeliness of issuing the original card. We discuss these limitations in Recommendation No. 7. In addition, the 108,000 figure includes all active patients as well as all applications received by Public Health, but not yet fully processed. Because our analysis was only on applications that had been fully processed, our figure cited in the chart would be lower than the monthly total reported by Public Health.			

In response to our analysis, Public Health staff stated that processing times have improved since December 2012. As a result, we requested a second dataset as of May 2013 and reperformed our analysis, focusing on red cards that had been issued from January through April 2013. We found that processing times improved significantly in this period with 99 percent of applications being processed within 35 days.

Although significant improvements have been made in application processing timeliness in Calendar Year 2013, we identified several issues explaining why Public Health has not always been able to process all red card applications within the 35-day constitutional deadline—issues that need to be addressed to ensure timeliness going forward. We describe these issues below.

Method for tracking processing times. Public Health currently tracks processing time by batch, rather than by individual card. Specifically, staff batch all applications received in a given day and keep them together until all applications have been completely processed and red cards are ready to be mailed to the applicants. Public Health then tracks the timeliness of the batch by comparing the date the batch was received to the date the red cards were mailed out. Using this

method, Public Health reported that it was processing applications in 30 days when it sent us the original dataset for our analysis and in 22 days when staff sent the second dataset.

We identified two main weaknesses with Public Health's batch approach. First, by not tracking timeliness by individual application, Public Health is not aware when a significant number of applications are being processed in an untimely manner. As a result, although Public Health may be processing its batches in a timely fashion, the individual experience for a significant number of applicants may be a delayed red card.

Second, the batch process does not adequately track the timeliness of "problem" applications. Problem applications are pulled from a batch for a variety of reasons, including incomplete information, lack of sufficient payment, or the need to confirm a new physician's authority to recommend marijuana. Once an application is pulled from a batch, its processing time is no longer tracked with the rest of the batch, which continues to move forward. Once the problem has been resolved, the application is placed with the current batch and processed as normal. However, Public Health does not track the amount of time it takes to resolve the problem that held up the application and does not have any internal, alternative processing deadlines for staff to follow in dealing with these problem applications.

Staff indicated that they do not consider problem applications to be subject to the 35-day constitutional deadline because these applications are not complete. This position appears reasonable for some circumstances, such as missing payments or missing information, but its appropriateness is less clear for other situations. For example, staff mentioned the lack of a current DEA registration by the recommending physician on file with Public Health as a type of problem application not subject to the 35-day deadline. However, the Colorado Constitution states that the first 30 days of the 35-day application process period is meant to "verify medical information contained in the patient's written documentation," which could reasonably include the physician's updated DEA registration information. Public Health does not track the reasons why problem applications get pulled from batches, so we could not perform a comprehensive analysis to determine whether staff were inappropriately excluding some problem applications from measurement against the 35-day standard. We also could not determine if the late applications identified in our analysis above are mostly the result of problem applications that Public Health should not be expected to process within 35 days.

Inefficiencies in processing applications. Public Health staff indicated that many "lean" projects have been undertaken to address inefficiencies in the application review and card-issuing processes. We reviewed the results of these projects and found that Public Health had started at least 11 lean projects in Fiscal Years 2012

and 2013 related to its red card application processing. At the time of our review in May 2013, it appeared that Public Health had been able to identify ways to make its processing more efficient, as evidenced by the improvement in application processing times since January 2013 reported above. However, the final results of all these projects were not yet known by the end of the audit, so Public Health should continue to monitor whether these projects are improving efficiency and should implement new lean projects if inefficiencies remain.

Performance measurement. Public Health has not established performance measures for processing red card applications. Measuring performance in meeting an agency's core function or mandate, such as issuing red cards within 35 days, is important because it helps ensure that government is held accountable for the services it delivers and can help focus staff on accomplishing the desired performance. One possible performance measure that Public Health could use for its red card application process is the percentage (e.g., 90 or 95 percent) of applications that are processed within the 35-day constitutional deadline. A performance measure such as this would promote the efficient processing of applications while also recognizing that some problem applications cannot reasonably be processed that quickly.

Public Health publishes a monthly "Program Update" on its website, outlining information about the number of and demographics of card holders, but this monthly update does not include any information about the timeliness of the application process as a way to measure Public Health's performance in administering the medical marijuana program. Public Health also does not include any performance measures in its SMART Government strategic plan about the timeliness of Registry application processing.

Recommendation No. 2:

The Department of Public Health and Environment should improve the timeliness of processing Medical Marijuana Registry applications by:

- a. Developing and implementing mechanisms for tracking the timeliness of individual applications, the reasons that "problem" applications need to be pulled out of daily batches, the number of applications that are pulled out of daily batches, and the amount of time it takes to resolve problem applications.
- b. Establishing clear criteria for the types of "problem" applications that are or are not subject to the 35-day constitutional deadline for the completion of processing and implementing alternative processing deadlines that apply in these "problem" cases.

- c. Using the data collected in part “a” to regularly monitor the timeliness of individual applications and analyze the causes for untimely processing.
- d. Monitoring whether the “lean” improvements are enhancing efficiency and undertaking additional “lean” projects related to application processing if inefficiencies remain.
- e. Developing and implementing a performance measure related to timely processing of applications and reporting on its performance to stakeholders.

Department of Public Health and Environment Response:

- a. Agree. Implementation date: September 2013.

The Department will develop and implement mechanisms for tracking the timeliness of individual applications, the reasons that “problem” applications need to be pulled out of daily batches, the number of applications that are pulled out of daily batches, and the amount of time it takes to resolve problem applications.

- b. Agree. Implementation date: September 2013.

The Department will establish clear criteria for the types of “problem” applications that are or are not subject to the 35-day constitutional deadline for the completion of processing and implementing alternative processing deadlines that apply in these “problem” cases.

- c. Agree. Implementation date: September 2013.

The Department will use the data collected in part a to regularly monitor the timeliness of individual applications and analyze the causes for untimely processing.

- d. Agree. Implementation date: December 2013.

The Department will measure whether the “lean” improvements are enhancing efficiency and undertake additional “lean” projects related to application processing if inefficiencies remain. The Department will conduct at least two more “lean” events.

e. Agree. Implementation date: August 2013.

The Department will develop and implement a performance measure related to timely processing, and report on its performance to stakeholders.

Designating a Provider

As previously discussed, patients access medical marijuana through two primary means: growing it themselves or obtaining it from a provider. According to May 2013 information from Public Health, 57 percent of patients designate a marijuana provider; the rest are presumed to be growing their own marijuana. These designated providers are either caregivers, who grow marijuana on behalf of specific patients, or dispensaries that are affiliated with grow operations that can grow marijuana for a specific group of patients. As of May 2013, about 50,000 individuals had designated a dispensary and 5,500 individuals had designated a caregiver as their provider for medical marijuana. Individual patients, caregivers, and dispensaries are all limited in the amount of marijuana they can possess. A patient and his or her designated caregiver can collectively possess six plants and 2 ounces of marijuana [Colorado Const., art. XVIII, sec 14(2)(a)(III)], or greater amounts if medically necessary for the patient's debilitating condition [Colorado Const., art. XVIII, sec 14(4)(b)]. Dispensaries and their affiliated grow operations can grow marijuana for a specific group of patients who have designated them as their primary provider, and the amount they can grow and possess is limited to the amount authorized for that specific group of patients [Section 12-43.3-901(4)(e), C.R.S.]. These controls over how much marijuana individuals and providers can possess is an important feature of the vertical integration model for medical marijuana discussed in the *Medical Marijuana Regulatory System, Part I Performance Audit* (March 2013). This model seeks to ensure that marijuana is used only for patients' legitimate medical needs and is not diverted outside the system.

Statute requires individuals who apply to the Registry to indicate whether they plan to (1) grow their own medical marijuana, (2) obtain medical marijuana from a primary caregiver, or (3) obtain medical marijuana from a medical marijuana dispensary [Section 25-1.5-106(8)(f), C.R.S.]. If individuals plan to obtain medical marijuana from a caregiver or a dispensary, statute requires the patient to designate the caregiver or dispensary on his or her red card application. Patients are required to notify Public Health within 10 days if they change their designated provider by submitting a change request form [Colorado Const., art. VIII, sec. 14(3)(f) for caregivers and Regulation 4A for all other changes]. When Public

Health receives this form, staff update the patient's record in the Registry with the new provider.

Public Health reported that patients change providers often to take advantage of special deals that dispensaries offer to patients who designate them as their providers. We reviewed Calendar Year 2012 data and found that a small group of patients submit a significant number of change requests. Specifically, 160 patients made more than 10 change requests each in 2012. Conversely, about 23,100 (78 percent) of patients who submitted change requests in 2012 submitted just one change request.

Public Health maintains a list within the Registry of how many patients have designated a certain provider as their source for marijuana and, therefore, how much marijuana each provider is entitled to possess. We assessed whether the list of patients affiliated with each dispensary and caregiver was accurate and useful by interviewing staff from Public Health and Revenue and reviewing non-personally-identifiable change request data from the Registry to analyze the frequency of patients' change requests and Public Health's processing times. Overall, we found that there was little value in requiring patients to notify Public Health of their providers and requiring Public Health to maintain that information because (1) this information is not being used under the current regulatory structure, (2) the provider data maintained by Public Health has not been accurate, and (3) there appears to be a better way to monitor whether providers possess no more medical marijuana than they are allowed. We discuss these findings below.

Unused provider information. It is not clear that the provider designation information compiled by Public Health is currently being used on a regular basis by any government entity, which suggests that collecting the information is not useful. For example, the most logical user of the dispensary information would be Revenue, which could theoretically use the information to determine whether dispensaries have excessive marijuana plants and product given the number of patients who have designated them. However, Revenue has in practice not relied on Public Health for this information because of Public Health's processing delays, which we discuss below, and because Revenue can obtain similar information about patient designations directly from dispensaries. In addition, it is not clear that Revenue has the authority to access provider designation information from Public Health because of confidentiality provisions in the Constitution. We discuss these confidentiality issues in more detail in Chapter 3. Public Health staff reported that they interpret constitutional references to caregivers to include dispensaries. However, Amendment 20 did not contemplate the existence of retail medical marijuana dispensaries. In addition, the Constitution defines caregivers as individuals who assume significant responsibility for managing a patient's well-being, which should include activities beyond growing and cultivating medical marijuana for patients. We did not find

any evidence to suggest that dispensaries provide any caretaking services; their primary purpose is to sell medical marijuana.

With regard to caregiver information, law enforcement officials reported that when they investigate a caregiver, they need to confirm which specific patients have designated that individual as their caregiver. However, law enforcement told us they have encountered difficulty confirming caregiver information with Public Health, because Public Health has a policy stating that staff “will not disclose primary caregiver information” when verifying a patient’s red card for law enforcement.

Inaccurate data. The provider designation information maintained by Public Health has been inaccurate because Public Health has not been processing provider change requests in a timely manner. Specifically, Public Health staff reported in December 2012 that they were processing change requests received in August 2012, meaning that Public Health was about 4 months behind in processing these requests. Further, we analyzed Registry data and determined that the average processing time for the 43,000 change requests submitted by patients in Calendar Year 2012 was 128 days with 91 percent of the requests taking more than 90 days to process. The longest processing time was more than 1 year, at 369 days.

In addition, staff reported that Public Health does not inform patients if their change request form is rejected. Public Health may reject a provider change request for a variety of reasons, such as the request being filled out incompletely or information being crossed out, and rejections are not uncommon. In Calendar Year 2012, Public Health rejected 29 percent of the nearly 43,000 change requests it received. As a result of not informing patients that their change request has been rejected, patients use the provider they were trying to switch to, even though that provider has no legal basis to grow marijuana for that patient.

Subsequent to our original analysis, Public Health reported that it had caught up on all pending change requests and has begun to inform patients when their change requests are rejected. It appears that Public Health eliminated this backlog by having staff work overtime in January 2013 to complete the outstanding requests. It was unclear by the end of the audit whether Public Health would be able to remain current on provider change requests.

Finally, statute does not prohibit a dispensary from selling medical marijuana to an individual who has a red card but has not designated that particular dispensary as his or her medical marijuana provider. As a result, the designation information that Public Health collects may not accurately reflect where patients are obtaining their medical marijuana.

Better method. Given the passage of Amendment 64, a new approach may be warranted for ensuring that marijuana providers are not producing more marijuana than is needed by patients with legitimate medical needs. Specifically, the requirement for patients to affiliate with dispensaries may no longer make sense with the legalization of recreational marijuana, which does not require that customers designate a particular store from which they will buy their recreational marijuana. Further, Revenue staff indicated that a marijuana inventory tracking system that Revenue is currently developing for the medical and recreational marijuana industries will be a more efficient and effective mechanism for ensuring that marijuana is not diverted outside the industry than trying to track which patients have affiliated with which dispensary.

Decoupling the link between patients and dispensaries would likely require statutory change. For example, as mentioned previously, statute requires individuals to designate a provider, if they intend to use one, when applying for a red card. In addition, Section 12-43.3-901(4)(e), C.R.S., makes it unlawful for any dispensary to possess more than six marijuana plants and 2 ounces of useable marijuana for each patient who has designated the dispensary as his or her provider. If the State adopted a model in which medical marijuana inventory was tracked similarly to the way that Revenue intends to track recreational marijuana inventories (i.e., through a centralized inventory tracking system), these provisions of statute would be obsolete.

Whether to decouple the link between patients and caregivers is a more difficult question. Statute [Section 25-1.5-106(7)(d), C.R.S.] requires a caregiver to provide law enforcement upon request with the red card number of each patient who has designated the caregiver as his or her provider. Law enforcement can then check with Public Health to see whether the patients or the caregiver are on the Registry. Even so, it is possible that some or all of the card numbers given to law enforcement by the caregiver will represent patients who have subsequently switched to other caregivers. Therefore, law enforcement may need Public Health to verify on an aggregate basis how many patients have designated a caregiver as their provider.

In the next section of the report, we discuss the issue of caregivers in more general terms and make recommendations to improve the oversight of these individuals, which will also address the caregiver issue raised in this section of the report. We also discuss issues and make recommendations related to the confidentiality of Registry data in more detail in Chapter 3.

Recommendation No. 3:

The Department of Public Health and Environment (Public Health) and the Department of Revenue should work together and with stakeholders, as appropriate, to determine if Public Health can discontinue maintaining information about which medical marijuana dispensary individuals on the Medical Marijuana Registry have designated as their provider. If the determination is that this information is not necessary, then Public Health should discontinue collecting this information, and both departments should work with the General Assembly, as necessary, to revise statute to implement this change of policy.

**Department of Public Health and Environment
Response:**

Agree. Implementation date: May 2014.

The Department of Public Health and Environment (Public Health) has received requests from the Department of Revenue regarding which medical marijuana dispensary individuals on the Medical Marijuana Registry have designated as their provider. If the Department of Revenue determines this information is not necessary, then Public Health will discontinue collecting this information, and will work with the General Assembly, as necessary, to revise statute to implement this change of policy.

Department of Revenue Response:

Agree. Implementation date: July 2014.

The Department of Revenue will work together with the Department of Public Health and Environment (Public Health) and stakeholders to determine if Public Health should discontinue maintaining information about which dispensary an individual has designated as their provider. If it is determined that this information should not be collected, the Department of Revenue will work with Public Health and the General Assembly to revise statute to implement the change.

Oversight of Caregivers

The General Assembly has been clear in expressing its desire that rules be implemented to prevent individuals who are not suffering from a debilitating medical condition from gaining access to medical marijuana [Section 25-1.5-106(1)(b), C.R.S.]. The General Assembly addressed this issue in House Bill 10-1284, which created the vertical integration regulatory model for medical marijuana that is intended to ensure that medical marijuana grown, processed, and sold in Colorado does not enter the recreational market or cross state borders. Although Revenue is mostly responsible for implementing and monitoring the vertical integration model through its regulation of medical marijuana businesses (e.g., dispensaries that sell medical marijuana), the General Assembly has also given Public Health oversight duties that are important for preventing the diversion of medical marijuana. Specifically, Public Health is primarily responsible for overseeing caregivers, which also provide medical marijuana to patients. As a result, Public Health has a role to play in ensuring that Colorado's medical marijuana is not diverted outside the industry. Revenue is also responsible for providing some oversight of caregivers in addition to its duties related to medical marijuana businesses.

To support the vertical integration model envisioned by the General Assembly for medical marijuana, an effective system needs to be in place for overseeing caregivers. Such a system would ensure that caregivers are performing services required by statute and minimize the risk that caregivers are diverting medical marijuana from the system. Specific requirements that currently exist for caregivers include:

- **Role of Caregivers.** The Colorado Constitution defines caregivers as individuals who have “significant responsibility for managing the well-being of a patient who has a debilitating medical condition” [art. XVIII, sec. 14(1)(f)]. State regulations further establish that significant responsibility means “in addition to the ability to provide medical marijuana, regularly assisting a patient with activities of daily living, including but not limited to transportation or housekeeping or meal preparation or shopping or making any necessary arrangement for access to medical care or other services unrelated to medical marijuana” (Section 2.A.iii, 5 CCR 1006-2). State regulations go on to state that “the act of supplying medical marijuana or marijuana paraphernalia, by itself, is insufficient to constitute ‘significant responsibility for managing the well-being of a patient’” (Section 2.A.iii, 5 CCR 1006-2). In 2009, the Colorado Court of Appeals also concluded that to qualify as a caregiver under the Constitution, “a person must do more to manage the well-being of a patient who has a debilitating medical condition than merely supply marijuana” (*People v. Clendenin*).

- **Placement on the Registry.** Section 25-1.5-106, et seq., C.R.S., contemplates a regulatory system of caregivers in which they apply to Public Health for placement on the Registry. Specifically, to be considered in compliance with the constitutional provisions related to medical marijuana, caregivers are required to have a red card issued by Public Health in their possession at all times that they are in possession of any form of medical marijuana [Section 25-1.5-106(9)(a), C.R.S.]. In developing the application on which caregivers apply for placement on the Registry, Public Health may require caregivers to make an attestation that the caregiver has significant responsibility for managing the well-being of the patient for whom he or she is designated as the caregiver [Section 25-1.5-106(3)(b)(II), C.R.S.]. Public Health may deny a caregiver's application for placement on the Registry or revoke a caregiver's red card if Public Health determines that the caregiver is in violation of requirements in the Constitution, statutes, or regulations [Section 25-1.5-106(9)(b), C.R.S.].
- **Five-Patient Limit.** Statute [Section 25-1.5-106(8)(a), C.R.S.] limits caregivers to serving no more than five patients at any given time. However, the law grants Public Health authority to allow caregivers to serve more than five patients in "exceptional circumstances." Statute does not define what constitutes "exceptional circumstances," although the law specifically mentions the proximity of dispensaries to the patient as a factor that Public Health may consider when making that determination. State regulations specify the following factors that Public Health must consider when acting on a caregiver's request to exceed the five-patient limit:
 - Information submitted by the patient
 - Information submitted by the caregiver
 - The proximity of dispensaries to the patient
 - Whether granting a waiver to the five-patient limit would either benefit or adversely affect the health, safety, or welfare of the patient
 - What services beyond providing medical marijuana the patient needs from the caregiver

State regulations also allow Public Health to specify terms and conditions under which a waiver to the five-patient limit is granted and which terms and conditions must be met for the waiver to remain in effect.

- **Registering Grow Locations.** Statute [Section 25-1.5-106(7)(e), C.R.S.] requires caregivers to register the location of their medical marijuana cultivation operations with Revenue so that Revenue can provide this information to local governments and law enforcement agencies

conducting enforcement activities. Statute also requires that caregivers provide Revenue with the red card identification number of each patient they are serving.

We reviewed the policies and procedures Public Health and Revenue have in place for regulating caregivers to determine if they are effective controls for ensuring that caregivers are complying with the law and for preventing the diversion of Colorado's medical marijuana. Overall, we found that the State has not developed an effective system for overseeing the activities of caregivers. Specifically, in the sections below, we discuss various issues that we identified suggesting caregivers have been operating without significant scrutiny or regulation, even though they play a key role in providing medical marijuana to patients.

- **Role of Caregivers.** Although the Colorado Constitution and state regulations require caregivers to do more than provide medical marijuana to patients, we found that Public Health has not taken steps to verify or even question whether caregivers have assumed "significant responsibility for managing the well-being" of the patients they serve. We reviewed the application on which patients designate a caregiver and found that it only requires the caregiver's contact information, date of birth, and a copy of his or her photo identification. The application does not require any information describing the additional assistance caregivers will provide beyond supplying the patient's medical marijuana, nor does the application require caregivers to attest that they are assuming significant responsibility for managing the patient's well-being. As a result, this form is an ineffective control for ensuring that caregivers are providing the services required by the Colorado Constitution.
- **Placement on the Registry.** Although Public Health has the authority to create a caregiver application form to include, at minimum, an attestation that the caregiver has significant responsibility for the patient's well-being, and to deny or revoke a caregiver's red card, we found Public Health has not developed a caregiver application, does not issue red cards to caregivers, and does not have a process for revoking a caregiver's placement on the Registry. Caregivers are placed on the Registry only when listed on a patient's application. As a result, Public Health does not have an effective method for overseeing caregivers. For example, Public Health does not require that caregivers specify the responsibilities they have for the patients under their care, nor does it require caregivers to show proof of having registered their grow location with Revenue. In addition, since Public Health does not issue red cards to caregivers, caregivers can only provide law enforcement information associated with

their patients' red cards to demonstrate that the caregivers are operating within the law.

- Five-Patient Limit.** As of December 2012, Public Health's records indicate that there were about 5,400 caregivers serving about 8,500 patients. The total number of patients on the Registry was approximately 108,000. According to staff, in December 2011 Public Health implemented a process through which patients can apply for a waiver that allows their designated caregiver to serve more than five patients. If a caregiver wishes to serve more than five patients, each prospective patient who wants to designate a caregiver already serving five patients must submit a waiver form that includes information such as how granting a waiver would benefit that patient's health, safety, and welfare and what services beyond supplying medical marijuana the patient requires. According to Public Health, as of December 2012 it had approved patient limit waivers for caregivers associated with 184 active patients. We reviewed caregiver data and determined that as of December 2012, there were 52 caregivers serving more than five patients each. The number of patients these caregivers served ranged from six patients to 37 patients. The table below shows a breakdown of how many caregivers were serving specified numbers of patients.

Number of Patients Served By Caregivers With Approved Caregiver's Patient Limit Waivers December 2012	
Number of Patients	Number of Caregivers Serving Each Number of Patients
6	28
7	8
8	3
9	2
10	4
11	1
12	2
15	1
20	1
25	1
37	1
Source: Office of the State Auditor's analysis of caregiver data provided by the Department of Public Health and Environment.	

Although we could not access and review specific waiver forms because they contain confidential patient and caregiver information, our review of Public Health's process for granting waivers identified several concerns. First, Public Health's procedure does not define what constitutes "exceptional circumstances" or establish parameters to help staff determine whether those circumstances exist. For example, the waiver form asks whether any dispensaries are located within 5 miles of the patient so staff can consider the proximity of dispensaries to the patient. However, Public Health has not defined what an appropriate distance between a patient and the nearest dispensary should be to create an exceptional circumstance. Further, because some local authorities have prohibited dispensaries, patients in certain geographical areas may have a greater need to designate a caregiver. However, Public Health does not maintain information about which local jurisdictions have prohibited dispensaries.

A related concern is that Public Health does not appear to evaluate the reasonableness of the information provided on the waiver forms. According to staff, they review the waiver forms for superficial factors, such as whether any information has been crossed out. Staff told us they have rejected a "small number" of waiver forms because they contained this type of technical error, or because the forms were submitted without an accompanying red card application, which Public Health requires. Otherwise, Public Health approves the waiver forms as long as they are filled out completely. Staff also told us they do not "judge" the reasons a patient is requesting approval for his or her designated caregiver to serve more than five patients. For example, staff told us a patient could indicate that employees at a nearby dispensary are unfriendly, and Public Health would consider that an acceptable reason to approve the waiver request and allow the patient to switch to a caregiver who already has five patients. Staff also do not review the list of additional services (i.e., beyond just supplying medical marijuana) that the caregiver will be providing to the patient to determine if these services meet the "significant responsibility" standard in the Constitution. Public Health's approach may not fulfill the General Assembly's intent that caregivers may not serve more than the statutory maximum of five patients except under "exceptional circumstances," and the approach does not ensure that caregivers are doing more than just selling marijuana to their patients.

- **Registering Grow Locations.** We found that very few caregivers have registered with Revenue. Specifically, as of March 2013, only 28 caregivers had registered their grow locations, which represents about 0.5 percent of the caregivers in Public Health's records. In addition, out of these 28 records, seven contained missing or incomplete patient Registry

numbers, two did not include the caregiver's name, and one did not include the caregiver's address.

Our results indicate that the oversight of caregivers by Public Health and Revenue is weak. We identified two main consequences of this weak oversight: (1) caregivers may essentially be medical marijuana businesses but are not being regulated as such and (2) law enforcement does not have access to the information they need to verify the status of individuals claiming to be caregivers.

Caregivers as businesses. There is the risk that some caregivers may essentially be unlicensed medical marijuana businesses. For example, we found evidence showing that some caregivers appear to be operating substantial grow operations. We analyzed data showing the amount of marijuana that registered caregivers operating in December 2012 were allowed to grow and possess on behalf of their patients. We found that the quantity of marijuana plants caregivers were allowed to possess ranged up to 519 plants. Similarly, the number of ounces of marijuana caregivers were allowed to possess ranged from 2 to 125 ounces (which equates to about 8 pounds of marijuana). By comparison, we reviewed data on dispensaries from Public Health as of December 2012 and found numerous examples of dispensaries that were not authorized to possess more than 519 marijuana plants or 125 ounces of useable marijuana.

In addition, individuals may be choosing to become caregivers, rather than licensed business owners, to avoid the scrutiny that is placed upon licensed medical marijuana businesses. Specifically, in one licensing file we reviewed as part of our sample during our *Medical Marijuana Regulatory System, Part I Performance Audit* (March 2013), we found evidence that an applicant for a business license had decided to withdraw his or her application and continue operating as a caregiver instead.

We also did not find any evidence to suggest that Public Health or Revenue have considered whether a distinction should be made between caregivers who serve a small number of patients and caregivers who grow and cultivate large amounts of medical marijuana. Further, no policies or procedures were in place to help the State determine how caregivers should be classified and whether they should have to obtain a medical marijuana business license if they met certain criteria, such as the size of their medical marijuana plant inventory.

If some caregivers are actually small-scale businesses but are not being regulated as such, it means that these caregivers are legally growing significant amounts of medical marijuana without being subject to any of the security, safety, and other regulations that apply to licensed businesses that grow and sell medical marijuana. For example, caregivers are not subject to the financial and background investigations that medical marijuana business owners undergo before being licensed. Caregivers are also allowed to operate in municipalities that have

banned medical marijuana businesses without any oversight by the local government. In addition, caregivers do not pay sales tax on marijuana they sell, which could give them an unfair competitive advantage over licensed businesses.

Finally, the lack of scrutiny over caregivers who are essentially operating as businesses increases the risk that medical marijuana will be diverted outside the industry. Specifically, law enforcement officials we interviewed said they have observed a relationship between caregivers and the diversion of medical marijuana to the black market. For example, one official told us anecdotally about a caregiver who ran an online marijuana distribution business for anyone who wished to purchase marijuana. Another official said caregivers contacted by law enforcement have said they operate under the guise of being caregivers, but they make money by charging fees to grow marijuana plants for people who are not registered medical marijuana patients. Finally, as mentioned earlier in this chapter, an August 2012 report issued by the Rocky Mountain High Intensity Drug Trafficking Area noted various examples of medical marijuana from Colorado being diverted to the black market for recreational purposes by patients, caregivers, and dispensaries.

Lack of information for law enforcement. Since Public Health does not issue red cards to caregivers, law enforcement officers have no means by which to positively confirm that a caregiver is operating legally. Caregivers are asked to carry a copy of red cards issued to patients for whom they have been designated as caregiver. In practice, law enforcement officers attempt to confirm a caregiver's legitimacy by confirming with Public Health that the patient red cards a caregiver produces are valid. However, law enforcement cannot confirm that the caregiver has been approved by Public Health to serve patients who are placed on the Registry. In addition, Revenue's database of caregiver grow locations is intended to allow law enforcement to verify that marijuana being grown at a particular location is legal. Because the database currently does not capture the grow locations for more than 99 percent of caregivers, it is essentially useless to law enforcement for verifying that an individual is a caregiver.

Although Revenue has responsibilities for compiling caregiver grow locations, it has limited authority to ensure the information is useful to law enforcement. Specifically, Revenue does not have authority to know who has registered with Public Health as a caregiver, so Revenue cannot know whether the caregiver grow information that it compiles is complete.

Public Health has not been effective in administering some of the specific responsibilities given to it. For example, Public Health has not established a process for caregivers to indicate the significant responsibilities they are assuming for managing the well-being of their patients, for issuing red cards to caregivers, or for documenting the exceptional circumstances that require a caregiver to take on more than five patients. Further, Public Health staff told us they take a passive

approach to determining whether caregivers are complying with applicable state laws and regulations. Specifically, Public Health acknowledged that staff could choose to take administrative action against a caregiver, such as revoking the caregiver's designation on the Registry, but will do so only if Public Health receives information through a complaint that the caregiver is not providing additional services to patients beyond growing and cultivating medical marijuana. However, staff could not recall ever revoking an individual's right to act as a caregiver.

Finally, as discussed in the previous section, it is unclear whether Public Health still needs to maintain a list of patients on the Registry with their designated caregivers. As we discussed, this information is not being regularly used by any entity and is not always accurate. Even so, it is possible that this information would be important for law enforcement to use for verifying the status of individuals claiming to be caregivers.

Recommendation No. 4:

The Department of Public Health and Environment should strengthen its oversight of caregiver activities by:

- a. Developing and implementing policies and procedures for ensuring that caregivers are meeting constitutional and regulatory requirements for caregivers, including the provision that caregivers provide services beyond just providing medical marijuana to their patients. This could include implementing (i) an application for caregivers to apply for placement on the Registry, (ii) a process to issue red cards to caregivers, and (iii) policies and procedures for denying a caregiver's application and revoking a caregiver's red card. Public Health could also revise the patient red card application to include an attestation that caregivers are assuming significant responsibility for managing the patient's well-being and a section for caregivers to indicate what services beyond growing and cultivating medical marijuana they will provide.
- b. Enhancing its policies and procedures for reviewing and approving waivers for caregivers to serve more than five patients to ensure that caregivers only serve additional patients when exceptional circumstances exist. These changes should include defining the term "exceptional circumstances" in a manner that would prevent caregivers from using the waiver to avoid becoming a licensed medical marijuana business.
- c. Working with Revenue as appropriate to (i) determine whether additional criteria are needed (e.g., number of people served, number of plants

cultivated, and/or amount of finished marijuana product possessed) to identify a clear threshold that would differentiate caregivers from licensed businesses in Colorado's medical marijuana regulatory scheme, (ii) implement policies and procedures for determining whether an individual should be classified as a caregiver or should be required to obtain a business license, and (iii) work with the General Assembly as necessary to implement the proposed changes in criteria and policies and procedures.

Department of Public Health and Environment Response:

- a. Agree. Implementation date: January 2014.

The Department will revise the patient red card application to include an attestation that caregivers are assuming significant responsibility for managing the patient's well-being, and add a section for caregivers to indicate what services beyond growing and cultivating medical marijuana they will provide. The Department will also provide guidance for staff who review the forms to determine if the prospective caregiver is in compliance with statute. The Department will also consider the other suggestions in the recommendation to determine whether any of these actions will enhance the Registry.

- b. Agree. Implementation date: December 2013.

The Department will enhance its policies and procedures for reviewing and approving waivers for caregivers to serve more than five patients to ensure that caregivers only serve additional patients when exceptional circumstances exist. These changes will include defining the term "exceptional circumstances" in a manner that would prevent caregivers from using the waiver to avoid becoming a licensed medical marijuana business.

- c. Partially agree. Implementation date: December 2013.

The Department does not currently have statutory authority to deny a caregiver request based upon the fact that a licensing regime exists under Department of Revenue (Revenue) oversight. The Department will work with Revenue to determine the statutory authority needed to define the difference between caregivers and licensed medical marijuana centers.

Auditor's Addendum:

Public Health indicates in its response that it does not have statutory authority to deny a caregiver request. However, Section 25-1.5-106(9)(b), C.R.S., appears to clearly give Public Health authority to deny an individual the right to be placed on the Registry as a caregiver as defined in the Colorado Constitution.

Recommendation No. 5:

The Department of Public Health and Environment (Public Health) and the Department of Revenue (Revenue) should work together with medical marijuana stakeholders to better define the role of caregivers in the State's medical marijuana system and improve the State's oversight of caregivers by:

- a. Evaluating the need to continue collecting information on which caregivers have been designated by individuals as their provider. If it is determined that Public Health should continue to collect this information, then Public Health should take steps to ensure that this information is updated and accurate.
- b. Determining whether Public Health or Revenue needs greater statutory authority to effectively regulate caregivers and, if so, present proposed changes to the regulation of caregivers to the appropriate interim Committee of Reference for consideration and work with the General Assembly as necessary to implement these changes.

Department of Public Health and Environment Response:

- a. Partially agree. Implementation date: June 2013.

The Department believes that the constitution requires the Department to collect information on which caregivers have been designated by individuals as their providers. The Department has updated caregiver information so that it is up-to-date and accurate.

Auditor's Addendum:

Public Health indicates in its response that it believes the Colorado Constitution requires the collection of caregiver information. We believe it is unclear that the constitution requires Public Health to maintain this data and on the basis of our audit work we question

the value of Public Health continuing to collect and maintain data on the caregivers who supply medical marijuana to patients for three primary reasons: (1) no government entity routinely uses the information, (2) the information was not accurate at the time of the audit, and (3) it may be more effective to regulate providers through other means.

- b. Partially agree. Implementation date: December 2013.

The Department's existing resources for the Medical Marijuana Registry are fully utilized in the processing of applications from patients, and are insufficient to support a greater regulatory role with respect to approximately 5,400 individual primary caregivers. The Department will meet with representatives from the Department of Revenue to determine whether an effective regulatory model could be developed to strengthen the oversight over primary caregivers, and in so doing will work with the Attorney General's Office to determine whether greater statutory authority is needed to implement such a model.

Auditor's Addendum:

Public Health indicates in its response that its resources are insufficient to support a more extensive role in regulating caregivers. This recommendation does not assume that more resources to carry out regulation would be required, but rather suggests that the departments evaluate the sufficiency of their statutory authority in this area. As such, the potential need for additional resources may not be at issue.

Department of Revenue Response:

- a. Agree. Implementation date: July 2014.

The Department of Revenue will work together with the Department of Public Health and Environment (Public Health) to evaluate the value of Public Health continuing to collect information on which caregivers have been designated by individuals as their provider.

- b. Partially agree. Implementation date: July 2014.

The Department of Revenue will work together with the Department of Public Health and Environment (Public Health) to determine if greater statutory authority needs to be established to effectively

regulate caregivers. Caregivers are akin to healthcare providers, which should be under the purview of Public Health, who has the expertise and experience to determine whether or not a caregiver is meeting established requirements to manage the well-being of a patient with a debilitating medical condition. The Department of Revenue is responsible for the regulation of marijuana businesses that cultivate, manufacture, and distribute marijuana as lawfully provided for by Colorado law. To be clear, the Department of Revenue does not currently have the authority or expertise to regulate caregivers, and we believe that Public Health has the information, resources, and expertise available to effectively oversee the caregiver model. The Department of Revenue is willing to assist Public Health by sharing our experience and expertise in an effort to establish sound public policy in this area, which includes discussing controls to ensure caregivers register their cultivation operations with Revenue.

Auditor's Addendum:

Both Public Health and Revenue have responsibilities related to caregivers. Section 25-1.5-106(7)(e), C.R.S., requires caregivers to provide the location of their medical marijuana cultivation operations to Revenue so that Revenue can verify the location to a local government or law enforcement agency upon request. Further, Section 12-43.3-307(1)(k), C.R.S., prohibits Revenue from issuing a business license to an individual whose authority to serve as a caregiver has been revoked by Public Health. Therefore, having Revenue's involvement in evaluating the current regulatory authority over caregivers is important, particularly if Public Health begins to more actively regulate caregivers.

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Program Administration

Chapter 3

As previously discussed, the Department of Public Health and Environment (Public Health) is responsible for administering the Medical Marijuana Registry (the Registry). These responsibilities broadly include issuing red cards to qualifying patients, maintaining the Registry database, and setting fees to cover the program's direct and indirect expenses. In Chapter 2 we discussed Public Health's controls over issuing red cards. In this chapter we discuss Public Health's management of the Registry data and of the associated fees and expenses. Throughout this chapter, we make recommendations to Public Health for improving its (1) management of the Registry's confidential data, (2) controls over the Registry database, (3) fee-setting activities, and (4) controls over expenses.

Management of Data

Public Health is responsible for managing the confidential database containing information about the patients who have applied to be on the Registry, as well as information about those patients' caregivers and physicians. As of December 2012, the database contained the records of more than 200,000 patients, nearly 108,000 of which were active records, representing patients with current, valid red cards.

We reviewed Public Health's management of Registry data to determine how well Public Health has maintained confidentiality of the data and to assess the sufficiency of information technology (IT) controls over the database. Overall, we found that Public Health has not always adequately safeguarded Registry data or ensured that only authorized individuals have access to the data. We also identified ways Public Health could improve its IT controls to ensure better data security, integrity, and availability. The following two sections discuss these issues.

Confidential Data

The Colorado Constitution [art. XVIII, sec. 14(3)(a)] establishes that the Medical Marijuana Registry is a confidential database and restricts who can access the information Public Health maintains about patients, caregivers, and physicians who recommend medical marijuana. Specifically, the Constitution states, "No

person shall be permitted to gain access to any information about patients in the state health agency's confidential registry, or any information otherwise maintained by the state health agency about physicians and primary care-givers, **except for authorized employees of the state health agency** 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" [emphasis added].

We assessed whether Public Health has maintained the confidentiality of Registry data in accordance with the Colorado Constitution. We analyzed the list of individuals with user access to the Registry as of October 2012, and we reviewed contracts between Public Health and entities whose staff have performed duties requiring Registry access. In addition, we interviewed Public Health staff and representatives from four law enforcement agencies around the state to determine what Registry access Public Health has allowed for individuals working on Public Health's behalf and for law enforcement.

Overall, we identified three main problems related to Public Health's management of confidential Registry data: (1) lack of controls over contractors and staff of other state departments whom Public Health has authorized to access confidential Registry data; (2) access by law enforcement officials/agencies of confidential Registry data under circumstances that the Colorado Constitution does not appear to allow; and (3) confidential data breaches. We discuss these issues in the sections below.

Controls over Registry access by contractors and staff of other state agencies. Public Health has authorized a variety of individuals, in addition to its own employees, to access confidential Registry data. These individuals include staff of two external contractors and of two other state agencies. The following table provides an overview of the entities whose staff have had access to confidential Registry information and the nature of their access.

Medical Marijuana Registry Entities With Access to Confidential Patient, Physician, and Caregiver Data			
Entity Name	Type of Access	Reason for Access	Number of Entity Staff with Access as of October 2012
Public Health	View and modify Registry records	Public Health staff are responsible for administering the medical marijuana program.	54
Colorado Health Emergency Line for Public Information (COHELP) ¹	Read-only access to all Registry data	Vendor staff provide call center services to respond to patient and other stakeholder inquiries. These staff have access to view Registry data as needed to answer caller questions.	22
Express Employment Professionals	Access to red card applications and ability to view and modify Registry data	From February 2010 through December 2012, temporary staff helped Public Health process high volumes of red card applications and input data into the Registry.	12
Division of Central Services ²	Access to red card applications and ability to view and modify Registry data	From August 2010 through November 2012, staff provided data entry and scanning services to help Public Health address increased workload from high volumes of red card applications.	7
Governor's Office of Information Technology (OIT)	System administrator access, which includes ability to view and modify Registry data	Senate Bill 08-155 required all IT support staff employed at individual state agencies (including Public Health) to become OIT employees, effective July 1, 2012.	7
Source: Office of the State Auditor's analysis of information from the Department of Public Health and Environment, contract documentation, and Senate Bill 08-155. ¹ COHELP is a division of Denver Health and Hospital Authority. ² The Division of Central Services is a division within the Department of Personnel & Administration.			

According to staff, Public Health hired contract staff to provide additional resources when the volume of red card applications began increasing significantly in Calendar Year 2009. Over the 4-year period from March 2009 to March 2013, the number of individuals with valid red cards increased from about 6,000 patients to 108,000 patients.

Because the Constitution indicates that access to the Registry is very limited—allowing access only to authorized employees of Public Health and to law enforcement agencies under certain circumstances—we obtained informal guidance from attorneys at the Office of Legislative Legal Services (OLLS) about whether Public Health was adhering to the Constitution when allowing staff of contract firms and other state agencies to access the Registry. OLLS attorneys advised us that, based on their review of the Constitution, it may be reasonable for Public Health to authorize individuals who provide services under an express or implied contract to access Registry data. OLLS attorneys also stated that in order to authorize such access, Public Health should have control over the details of the work performance of any authorized individuals.

We identified two problems related to Public Health’s authorizing contract and other state agency staff to access Registry data. First, Public Health does not maintain signed confidentiality statements for all staff of contract firms and other state agencies who have accessed the Registry. Public Health staff told us they require staff of contract firms and other state agencies to sign confidentiality agreements as a way of protecting confidentiality. The agreements include various provisions that require Registry users to agree to protect confidential Registry data and acknowledge their understanding that breaches of confidentiality could result in various disciplinary actions, including termination of employment or termination of the contractual agreement with Public Health. We reviewed confidentiality statements for a sample of 10 individuals from the Division of Central Services, Express Employment Professionals, and COHELP who had Registry access as of October 2012. Public Health could not provide signed confidentiality statements for three of the 10 staff in our sample. Public Health did not know if these individuals had never signed the agreements or if the statements had been misplaced. In either case, failing to obtain or maintain these signed confidentiality agreements undermines the effectiveness of this control.

Second, Public Health does not have adequate or consistent contract management practices to oversee the work performance of staff from contract firms and other state agencies, including ensuring that those individuals maintain confidentiality of Registry data. Specifically:

- Staff at COHELP, a division of Denver Health and Hospital Authority, provide call center services and field incoming calls from patients and other stakeholder inquiries. For example, patients may request the current status of their red card applications, if the applications are still under review. COHELP staff have been given access to view patient records in the Registry to help answer these types of questions. We reviewed Public Health’s contract with Denver Health and Hospital Authority for COHELP’s services and found that the contract does not include terms required under State Fiscal Rules, such as the scope of work, performance period, and payment terms for services related to the Registry; the contract

only discusses the scope of work for hotline services related to public health or bioterrorism issues that this contractor provides. In addition, although 95 percent of calls handled by COHELP in the past 2 years were related to medical marijuana, the contract is monitored by Public Health's Office of Emergency Preparedness and Response, not by staff of the medical marijuana program. As a result of the deficient contract and lack of monitoring, the medical marijuana program does not have control of the work performance of COHELP staff.

- Public Health had a contract with the Division of Central Services (Central Services) for Fiscal Year 2011, but the contract was not renewed for Fiscal Year 2012 or beyond. Although State Fiscal Rules do not require state agencies to implement contracts for services provided by other state agencies, the lack of a contract may limit Public Health's ability to exercise control over the work performance of Central Services staff who access the Registry. Public Health staff reported that they had identified problems with the quality and completeness of the scanning services that Central Services provided, causing Public Health staff to correct a substantial number of records.
- Public Health does not have a contract with the Governor's Office of Information Technology (OIT). As noted above, State Fiscal Rules do not require contracts between state agencies, but given the unique nature of the Registry and the constitutional protection of Registry data, Public Health could benefit from formalizing a contract with OIT. For example, a contract could outline requirements for OIT staff related to handling confidential Registry data and include provisions about remedies Public Health could pursue in case of a data breach.

Unallowable circumstances for accessing registry data. The Colorado Constitution [art. XVIII, sec. 14(3)(a)] allows authorized employees of state or local law enforcement agencies who "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" to verify their Registry status with Public Health. The Constitution further specifies that law enforcement officials can request Registry data "only for the purpose of verifying that an individual who has presented a registry identification card to a state or local law enforcement official is lawfully in possession of such card." This authority extends to the Department of Revenue's (Revenue) enforcement officers within the Marijuana Enforcement Division, who are considered peace officers while regulating medical marijuana businesses (Section 16-2.5-124.5, C.R.S.). We identified three areas in which law enforcement appeared to access Registry data under unallowable circumstances.

First, we reviewed a log of inquiries Public Health received from law enforcement agencies from January 2012 through August 2012. The log included seven

instances when Revenue staff sought to verify red card information about multiple patients at one time, ranging from five to 107 patients. According to Public Health, Revenue officers wanted to determine if a dispensary's medical marijuana inventory correlated to the amount of medical marijuana authorized for the dispensary's registered patients. Because Public Health does not maintain a centralized log of responses to law enforcement inquiries, we could not easily verify what information Public Health provided to Revenue in response. However, we question whether Revenue enforcement officers have legal authority to verify patient Registry data during their dispensary investigations, because it is unlikely that those officers have actually "stopped or arrested" every patient associated with a particular dispensary. It is also important to note that statute [Section 12-43.3-202(1)(d), C.R.S.] grants Revenue the authority to obtain patient information directly from dispensaries and use that information for law enforcement purposes. As we note in Recommendation No. 3, Public Health has not always kept this information updated, and Revenue reports that it has not regularly sought this information from Public Health.

Second, the mechanism giving law enforcement 24-hour access to Registry data appears to provide more information than allowed under the Constitution. Specifically, statute [Section 25-1.5-106(7)(d), C.R.S.] requires Public Health to make information about medical marijuana patients and caregivers "available 24 hours per day, 7 days a week" to law enforcement officers. This requirement was a provision within House Bill 10-1284 and became effective on July 1, 2010. Public Health established a mechanism to provide law enforcement 24-hour Registry access in April 2013.

Through an agreement with the Colorado Bureau of Investigation (CBI), Public Health implemented an automated interface between the Registry and the Colorado Crime Information Center (CCIC), a statewide computer system that delivers criminal justice information to law enforcement agencies. Using the interface, law enforcement officers can query a patient's name, date of birth, and red card serial number to determine if a patient's card is valid. If the patient has a record in the Registry, the interface generates a response that includes the patient's red card issuance and expiration dates, as well as the number of marijuana plants and ounces of medical marijuana that a physician recommended for the patient's medicinal use.

It is not clear that Public Health has constitutional authority to provide information about patient plant and ounce counts through the Registry-CCIC interface. The Colorado Constitution [art. XVIII, sec. 14(3)(a)] specifies that law enforcement shall be granted Registry access "only for the purpose of verifying that an individual who has presented a registry identification card to a state or local law enforcement official is lawfully in possession of such card." In the 2000 Blue Book, Amendment 20 proponents reiterated that law enforcement could access the Registry "to verify that an individual who is arrested for the possession

or use of marijuana is registered” with Public Health. Knowing the quantities of medical marijuana that patients and their caregivers can legally possess does not appear to be necessary to verify that an individual is lawfully in possession of a red card.

Third, we identified a potential confidentiality issue related to CBI’s maintenance of the interface between the Registry and CCIC. According to the agreement between CBI and Public Health, OIT support personnel at CBI will have access to at least 5 years’ worth of historical transaction logs that record every query generated through CCIC and the resulting Registry information. Although these staff work on behalf of a law enforcement agency, we question whether they have legal authority to access historical Registry data, because IT staff presumably are not stopping or arresting someone claiming to have a valid red card.

Confidentiality breaches. When the confidentiality of Registry data is breached, such as when a patient or other individual receives confidential information about someone else, Public Health has a procedure that requires staff to document information about the incident. Using incident reporting forms, staff document details about the incident, including what information was compromised, how Public Health remedied the situation, and what changes may help decrease the risk of a confidentiality breach in the future. We reviewed incident reporting forms for breaches that occurred from January 2009 through December 2012 and identified the following 15 confidentiality breaches:

- Patient information sent to the wrong recipients (5 incidents)
- Patient red cards sent to the wrong recipients (5 incidents)
- Incorrect caregiver listed on a patient’s red card (3 incidents)
- Patient information exposed to Public Health staff who do not perform work related to medical marijuana (1 incident)
- Names of all caregivers who were active as of December 2012 sent in a spreadsheet to the State Auditor (1 incident)

Public Health’s procedure requires staff to send a form letter notifying patients when their confidential information has been compromised. In addition, we found evidence in the incident reporting forms suggesting that Public Health also notifies caregivers when their confidentiality has been breached. During our review of the 15 incident reporting forms, we found two instances in which Public Health did not appear to notify the individuals whose confidential information was compromised. We discuss these issues in the following bullets.

- In one instance from December 2012, Public Health did not notify the 5,400 caregivers who were active as of December 2012 to inform them that their names were inappropriately provided to the State Auditor. According to guidance we obtained from the Office of the Attorney

General, the State Auditor cannot legally access personally identifiable data from the Registry, including caregiver names, despite the State Auditor's authority under Section 2-3-107(2)(a), C.R.S., to access state records. After we notified Public Health about this breach of confidentiality, Public Health provided us a new spreadsheet with caregiver names redacted. Public Health noted that one of the reasons it did not follow its policy to notify each caregiver is that it relied on the statutory confidentiality protections that apply to the State Auditor's work papers to prevent any further breach of this information.

- In another instance from January 2009, Public Health did not notify a patient whose information was exposed to a staff member who worked for the Water Quality Control Division within Public Health. Staff told us they did not notify this patient because the staff person who viewed the confidential information was a professional "working on state business." It is not clear what authority would allow any individual working on state business to view confidential Registry data. Further, the fact that Public Health staff completed an incident reporting form related to this incident suggests that Public Health considered this incident similar to other breaches of confidentiality. Therefore, we would have expected Public Health to handle the incident consistently and notify the patient whose information was compromised.

As the custodian of information about medical marijuana patients, caregivers, and physicians, Public Health has a responsibility to safeguard the confidentiality of individuals who participate in the medical marijuana program. Further, individuals whose information is stored in the Registry should be able to rely on Public Health to handle breaches of confidentiality consistently, regardless of whether permanent Public Health staff or contract staff were involved with the breach. In fact, the 15 specific breaches of confidentiality we identified involved both permanent Public Health employees and a staff person employed by OIT who was working on Public Health's behalf. Public Health's inconsistent responses to confidentiality breaches could undermine the confidence that medical marijuana program participants have in the State to protect their confidential information.

Colorado voters also anticipated that Registry data would be protected when they authorized Amendment 20, which granted the General Assembly authority to establish criminal penalties for confidentiality breaches of information provided to or by Public Health [Colorado Const., art. XVIII, sec. 14(8)(d)]. As such, Section 18-18-406.3(5), C.R.S., establishes that any officer, employee, or agent of Public Health who releases or makes public confidential Registry information without the written authorization of a medical marijuana patient commits a class 1 misdemeanor. According to Public Health, it did not pursue criminal charges against the staff involved with the breach of confidentiality incidents described in

this finding. Instead, in the majority of cases, Public Health changed its internal processes or advised the staff involved about how to prevent breaches in the future.

We identified four main causes of the issues described above which are discussed in the following bullets.

- **Lack of clear legal definitions governing registry access.** As mentioned previously, we consulted with attorneys from OLLS on the interpretation of constitutional and statutory provisions governing who can access Registry data and under what circumstances. OLLS indicated that Public Health may authorize individuals other than its own staff to access the Registry if those individuals are essentially serving in the capacity of employees, but statutes associated with Amendment 20 do not provide clear legal support or guidance to Public Health in authorizing such access. For example, statutes do not define “authorized employees of Public Health” or contain any other language to guide Public Health in authorizing access to the Registry. This issue affects access by contract staff and employees of other state agencies, such as OIT and Central Services, who have a legitimate business need to access the Registry.

OLLS staff also noted that there is a lack of clear statutory guidance about whether information on patient red card applications is subject to the same confidentiality requirements as information contained in the Registry itself. In particular, it is unclear whether pending applications are subject to the same confidentiality requirements as applications associated with patients who have been approved for a red card. This issue could have implications for what, if any, patient application information Public Health could be required to share in response to open records requests. Obtaining guidance from the Office of the Attorney General could assist Public Health in its interpretation of the statutes in this area.

- **Legal restrictions on law enforcement access to registry data.** We found that the legal restrictions on Registry access create barriers to the effective and efficient enforcement of the State’s medical marijuana laws by law enforcement agencies. Although the Colorado Constitution allows law enforcement to verify the validity of an individual’s red card, law enforcement representatives told us that officers also need to confirm how much medical marijuana patients are allowed to possess. Because the Constitution allows physicians to recommend more than the standard amount of medical marijuana (i.e., more than six plants and 2 ounces of a useable form of marijuana), law enforcement may encounter individuals who are lawfully in possession of significantly higher amounts.

As noted previously, Public Health already provides law enforcement with plant and ounce counts recommended by physicians for specific patients through the Registry-CCIC interface. However, in consultation with OLLS attorneys, we found that statutory change is needed to clarify Public Health's legal authority to provide that information. According to OLLS, the implementing statutes for Amendment 20 could be changed to add provisions that would authorize law enforcement agencies to access certain Registry data, including patients' specific medical marijuana recommendations. Another approach would be to define "confidential registry of patients" in statute to clearly indicate what information law enforcement can access as part of verifying the validity of a patient's red card.

Statutory changes related to law enforcement's access to physician recommendations would also benefit Revenue enforcement officers investigating the medical marijuana inventory that dispensaries maintain. However, as we discuss in Recommendation No. 3, this issue may become irrelevant if Public Health and Revenue determine tracking dispensary inventory by patient no longer makes sense given the methods that will be used for tracking inventory for recreational marijuana.

- **Inadequate protection of confidential data.** Public Health staff did not take the proper precautions to ensure that only appropriate individuals were exposed to confidential Registry data. Although Public Health has a procedure in place for handling breaches of confidentiality, Public Health did not ensure that staff followed the procedure consistently to inform all individuals whose information was compromised. Further, Public Health has not ensured that staff who sign confidentiality statements understand the importance of protecting the confidential data they can access and take appropriate steps to prevent confidentiality breaches from occurring.
- **Inadequate processes for confidentiality breaches.** Public Health reported that it assesses the risks associated with confidentiality breaches before notifying affected individuals. For example, Public Health decided not to notify the 5,400 caregivers whose information had been provided to the State Auditor because sending a letter to each of these individuals might further compromise confidentiality. Specifically, Public Health was concerned that if letters were sent to addresses where caregivers no longer resided, unauthorized individuals at those addresses might open the letters and obtain the caregivers' personal information. Further, Public Health relied on the statutory confidentiality protections that apply to the State Auditor's work papers to prevent any further breach of this information. Currently, Public Health's policy states that all affected individuals will be individually notified by form letter of any breach; it does not allow for other means of notification or indicate the risks of the notification process

will be assessed. A more flexible policy for notifying individuals whose confidentiality has been compromised could address this concern. For example, in the case of the 5,400 caregiver names that were provided inadvertently to the State Auditor, Public Health could consider posting a general notice on its website rather than sending a form letter to each individual.

Recommendation No. 6:

The Department of Public Health and Environment (Public Health) should ensure the confidentiality of patient, physician, and caregiver information in the Medical Marijuana Registry (the Registry) by:

- a. Seeking guidance from the Attorney General on what constitutes an “authorized employee” of Public Health who can be given access to the Registry and, based on the Attorney General’s guidance, working with the General Assembly as necessary to define “authorized employee” in statute.
- b. Seeking guidance from the Attorney General on whether protected Registry information includes pending applications that patients have submitted to obtain a red card and, based on the Attorney General’s guidance, working with the General Assembly as necessary to clarify in statute what information is protected Registry information.
- c. Seeking guidance from the Attorney General on what confidential Registry information, including the amount of medical marijuana physicians recommend for specific patients (i.e., plant counts and ounce counts), Public Health has authority to provide to law enforcement agencies, including through the Registry’s interface with the Colorado Crime Information Center, and based on the Attorney General’s guidance, working with the General Assembly as necessary to clarify in statute what information can be shared with law enforcement and under what circumstances.
- d. Developing and implementing policies and procedures for ensuring that all contracts involving the Medical Marijuana Registry are complete, accurate, and up-to-date and reviewing and amending as appropriate the contracts with Denver Health and Hospital Authority. Contracts should also include provisions that outline requirements for individuals accessing Registry data, including requirements to sign confidentiality statements.

- e. Revising its policy for handling confidentiality breaches to allow the flexibility to inform the affected parties in a way that minimizes further compromise of confidentiality.
- f. Ensuring that staff take proper precautions to protect confidential data and follow policies as revised in part “e” when breaches of confidentiality occur.

Department of Public Health and Environment Response:

- a. Agree. Implementation date: June 2014.

The Department will work with its attorneys to define what constitutes an “authorized employee” of Public Health who can be given access to the Registry and to provide clear guidance on permitting access to the Registry by individuals who do not meet the definition of an authorized employee of Public Health. The Department will also work with its attorneys to determine whether statutory or regulatory changes are needed to provide this clarity.

- b. Agree. Implementation date: December 2013.

The Department will seek an opinion from the Attorney General’s Office as to whether protected Registry information includes pending applications and based on the guidance will work with the General Assembly as necessary to clarify in statute what information is protected Registry information.

- c. Agree. Implementation date: December 2013.

The Department will seek an opinion from the Attorney General’s Office to clarify what confidential Registry information, including the amount of medical marijuana physicians recommend for specific patients (i.e., plants counts and ounce counts), the Department has authority to provide to law enforcement agencies, including through the Registry’s interface with the Colorado Crime Information Center. Based on the opinion received from the Attorney General’s Office, the Department will work with the General Assembly as necessary to clarify in statute what information can be shared with law enforcement.

- d. Agree. Implementation date: December 2013.

The Department will develop and implement policies and procedures for ensuring that contracts involving the Medical Marijuana Registry are complete, accurate, and up-to-date, and review and amend as appropriate the contracts with Denver Health and Hospital Authority. Contracts will include provisions that outline requirements for individuals accessing Registry data, including requirements to sign confidentiality statements.

- e. Agree. Implementation date: December 2013.

The Department will revise its policy for handling confidentiality breaches to allow the flexibility to inform the affected parties in a way that minimizes further compromise of confidentiality.

- f. Agree. Implementation date: September 2013.

The Department will ensure that staff take proper precautions to protect confidential data and follow established procedures and policies, as revised in part e, when breaches of confidentiality occur.

Database Controls

Information systems should have sufficient controls to ensure the security, integrity, and availability of data. Specifically, databases should (1) be secure and accessible to only authorized users, (2) contain data integrity controls that help prevent a user from entering inaccurate or incomplete information in key data fields, and (3) ensure the accessibility of data to their system users through regular backups of the data, including encrypting sensitive data contained in the database, and the development of disaster recovery plans that are regularly reviewed. We used State of Colorado Information Security Policies, guidelines published by the National Institute of Standards and Technology, and industry best practices to assess the sufficiency of IT control activities related to the Registry. This review consisted of interviewing staff at Public Health and OIT and testing general computer controls related to user access management, application development, data backups, and disaster recovery. To test the integrity of data contained in the Registry, we reviewed an extract of non-personally-identifiable data fields for all active records in the system as of December 2012 to look for missing or inconsistent data.

Overall, we found Public Health could improve its controls to ensure better security, integrity, and availability of Registry data. The problems with data

security include the issues raised in the previous section (Recommendation No. 6) about clarifying who represents the “authorized” employees of Public Health who can have access to the database, as well as encryption of data backups that do not conform to state information security policies, as discussed below. The problems with data integrity and data availability are described below.

Data integrity. Of the approximately 104,000 active records we reviewed as of December 2012, we found that 7,074 (7 percent) were either missing a key data point or contained a data point that was inconsistent with other data fields within the record. The issues we found are outlined in the bullets below. Some of the records (67) had multiple errors or missing data points. As we explain in the first bullet point, the great majority (representing 6 of the 7 percentage points) of the issues identified is a direct result of a limitation within the Registry. We note that the issues identified below are based on our ability to review only a limited amount of information for each record; we were unable to test whether personally identifiable information such as names, dates of birth, and application status are correctly represented in the Registry. The types of issues we found were as follows:

- 6,106 records had no information in the data field showing the expiration date of the physician’s Drug Enforcement Administration (DEA) certification. Statute requires that the physician have a current DEA certification to recommend medical marijuana for a patient [Section 25-1.5-106(2)(c)(III), C.R.S.]. Public Health reports that the great majority of these records (5,944) have a blank DEA field because of limitations within the system. If a physician is no longer eligible to recommend marijuana for patients (such as having a condition placed on his or her license or no longer holding a Colorado license), Registry staff “deactivate” the physician in the database by removing his or her DEA expiration date. This change propagates down throughout the database and causes the DEA date field to be removed from a patient’s record. A medical marijuana program employee may assume that a missing DEA date means that the patient’s applications must be denied because the physician is not eligible to recommend marijuana. However, we found 162 cases where the DEA date was missing for active physicians because of a data entry error by staff.
- 422 records had information showing the physician’s medical examination of the patient occurred *after* the application was received by the department. Public Health’s rules require that an applicant include his or her physician’s recommendation for medical marijuana, which must be based on an examination of the applicant, with the application materials.

- 147 records did not contain a medical examination date.
- 138 records had a mail date that was either blank or *before* the date when the application was received. This means that the system reported that a card was sent out before the application was even received.
- 298 records contained an issue date in the future, which is indicative of an incorrect issue date.
- 14 records had no information about when the application was received.
- 2 records indicated the application was received *after* the red card was issued.

These findings may indicate that some approved red cards were issued inappropriately. Because we could not view the underlying information, we could not follow up on these cases to make a determination about whether these cards were appropriately issued. We asked Public Health to look into the issues we found. Public Health staff reported that they determined all the issues were the result of data entry mistakes or system limitations.

Data availability. We found Public Health does not have sufficient processes to ensure the availability of Registry data for system users (i.e., Public Health staff), such as ensuring that users can see a record's history and ensuring access to data in the event of a disaster. Problems we found in this area are outlined in the bullets below:

- **Recording transactional history.** The Registry is not capable of recording and maintaining sufficient user history and record changes for all key fields. While Public Health has implemented recent upgrades to log changes made to the Social Security Number field (June 2012) and the Medical Marijuana Card Number (February 2013), there are still a number of key data fields that can be changed without being logged in the history. For example, the Registry does not log changes made to an applicant's name. Further, the Registry does not log any changes made to key date fields, including applicant date of birth, the date an application is received, the date a card is mailed, or the issue date of the card. These types of data points would be available in an applicant's case file, but the data are not captured within the Registry's log. This makes it more difficult for staff to spot abusive or fraudulent behavior, such as frequent changes in names or birth dates. Frequent changes to a patient's key identification fields may be done in order to give or sell valid cards to non-authorized individuals. For example, someone may send in a request asking for a name change. Although the change may only be to the last name and would appear to be

harmless, if staff sees a history of name changes made to the same record, they could easily recognize that someone is obtaining multiple cards, all with different last names. This may lead staff to conduct a more intense review of the request from the card holder.

Another example of a potential fraud is a Public Health employee going in and making name changes to a record, printing off a new card, and then giving or selling it to someone. After printing off the new card, the employee could change the name in the Registry back to that of the original card holder. While we did not find any of this type of fraud in our test work, and there are other mitigating controls in place over access to inventory of red cards, the current Registry system does not track name changes. Therefore, it would be very difficult for Public Health management to spot this type of fraudulent behavior.

Furthermore, the Registry is not designed to track which staff either view or modify an account, nor does it track which fields (with the exception of the Social Security Number and red card number fields) within an account were modified. For systems that capture sensitive data like the Registry, industry best practices suggest that the Registry should capture changes made to key data fields, such as changes in name, unique ID numbers, and other key fields used to track approved patients. Overall, the Registry lacks some of the necessary mechanisms for tracking data changes in key fields and the records that have been viewed by staff, which are important given the highly confidential and sensitive nature of the data.

- **Disaster recovery plan.** Public Health has not developed a disaster recovery plan for the Registry, and the Registry has not been included in any disaster recovery exercises. State Information Security Policies and industry best practices dictate that disaster recovery plans be developed, designed, and maintained in order to reduce the impact of a major disruption on key business functions and processes.
- **System backups.** We identified two issues with backups of Registry data. First, Public Health does not send backups of the Registry off-site. Instead, the backup files are stored on the Public Health's Storage Area Network (SAN). The backups are not stored on the same machine as the production (i.e., active) data, but they are stored in the same data center. Thus, if a disaster were to occur within Public Health's data center, and the disaster compromised both the Registry server and the SAN, the Registry could not be restored. Public Health has never experienced such an incident, but State Information Security Policies and industry best practices dictate that backups on production data be stored off-site. Public Health could solve this issue by either sending the data electronically to another data center or storing tape backups of the data in another building within Public Health's

campus. Second, Public Health does not encrypt backup files. We discussed the issue with OIT staff, who reported that the Registry's backup files are protected because they sit behind OIT firewalls and can only be accessed by authorized OIT staff. Notwithstanding these mitigating controls, State Information Security Policies require Public Health to encrypt backup files that contain the highest level of protected, confidential data known as Level 3 data, no matter where the data reside.

The lack of sufficient controls to ensure the availability and integrity of Registry data stem from the following: (1) the system being unable to log all of the changes made within patients' records, (2) the lack of sufficient controls as staff enter information into the Registry, and (3) the lack of processes to ensure that data are properly secured and can be restored in the event of a disaster. We discuss each of these issues below.

Immature system not designed to track transactional history. Overall, the Registry is an immature system that was not designed to handle as large of a database as it has become. When Public Health started to administer the medical marijuana program in 2001, it developed a system to record Registry applications by using a copy of a database table from the State's birth and death records table. This table was customized and changed to meet the needs of the Registry, which worked while the total number of patients on the Registry remained small from 2001 to 2009. However, as the number of patients began to dramatically increase in 2009, the need to capture historical data for an applicant became more important, and the overall needs of the Registry outgrew the capability of the system. As a result, the system is "immature" or not as fully developed as is necessary given the volume of transactions made each year, as well as the increased need to track and monitor transactional history.

Insufficient data input controls. Public Health has not established adequate data input controls dictating (1) the acceptable parameters for data entered into a particular field, such as the issue date cannot be before the application date, etc., and (2) which fields must be populated before a card can be issued (e.g., there must be a medical examination date before the card is issued).

Insufficient backup and disaster recovery plans. Public Health has not sufficiently overseen OIT in developing the backup and disaster recovery plans of the Registry. As stated, the Registry contains data that are classified as at the most sensitive level in the State (Level 3 data). As the business owner of the Registry, Public Health is required to ensure that the data be sufficiently secured. This means encrypting data from the Registry that is backed up. Furthermore, Public Health must ensure that the data custodian, in this case OIT, is sending the data off-site. Finally, it is the responsibility of Public Health to ensure that an adequate backup plan is developed and tested on a reasonable and regular basis.

In combination, these deficiencies increase the risk of system compromise and threaten the integrity and availability of Registry data. Information stored in the Registry is very sensitive, so it is essential that access to it be protected and limited. Because there is no method for program managers or OIT staff to determine or track which staff have viewed or modified a record, the risk of fraud or abuse is greater than if the Registry tracked the history of access to or changes within individual records. Additionally, because the Registry does not capture historical data, the system cannot identify which patients have been issued multiple cards over a given period. Therefore, staff cannot easily identify suspicious activity that may be abusive or fraudulent. If the Registry was tracking less sensitive information, then implementing these recommendations would not be as important. However, given that the Registry contains individuals' names, addresses, medical information, social security data, and birth dates, all of which are protected by the Colorado Constitution, Public Health should utilize more of the resources available to update the Registry.

Recommendation No. 7:

The Department of Public Health and Environment should improve the Medical Marijuana Registry's (the Registry) general computer controls by:

- a. Developing a system to capture and record which fields within a registrant's record were modified by a user within the Registry, and to provide historical information for key fields as identified by the business owner.
- b. Identifying fields that require data input controls and implementing those controls into the system.
- c. Developing a mechanism for identifying physicians that are no longer eligible to recommend medical marijuana.
- d. Creating a disaster recovery plan for the Registry so that it incorporates all critical components associated with the Registry and meets the requirements listed in Colorado Information Security Policies.
- e. Encrypting all backups of Registry data that contain any registrant records and sending encrypted Registry database backups to an off-site storage location.

Department of Public Health and Environment Response:

- a. Partially agree. Implementation date: May 2014.

Modifying the current computer system to accommodate these changes is not feasible. The Department will explore options to obtain resources to procure a computer system that meets these requirements.

- b. Partially agree. Implementation date: May 2014.

Modifying the current computer system to accommodate these changes is not feasible. The Department will explore options to obtain resources to procure a computer system that meets these requirements.

- c. Partially agree. Implementation date: May 2014.

Modifying the current computer system to accommodate these changes is not feasible. The Department will explore options to obtain resources to procure a computer system that meets these requirements.

Auditor's Addendum:

The Medical Marijuana Registry is a confidential registry intended to maintain an accurate record of individuals authorized to use marijuana for medical purposes. If modifying the system that currently houses the Registry is not possible, Public Health should take immediate steps to implement other controls to address risks identified in the audit. Public Health should not wait until it has explored options to procure a new system to strengthen controls over the sensitive data in the Registry.

- d. Agree. Implementation date: July 2013.

The Department has now created a disaster recovery plan that incorporates all critical Registry components and meets the requirements listed in the Colorado Information Security Policies.

- e. Agree. Implementation date: December 2013.

The Department will work with OIT to encrypt backup data and send it to an off-site location.

Fiscal Management

Public Health's medical marijuana program is funded by the annual application fee paid by patients, which generated a total of about \$16 million in Fiscal Years 2011 and 2012 combined. Over this 2-year period, program expenses totaled about \$5.1 million and covered the salary and benefits of its permanent staff (\$2.2 million total for 13.7 FTE in Fiscal Year 2011 and 32 FTE in Fiscal Year 2012), the use of outsourced temporary staff to work through a backlog of applications (\$1.5 million), the use of a contracted call center to provide customer service (\$50,000), and operational costs (\$1.4 million). The program shares some expenses with other programs within Public Health. For example, the program shares a director and three other FTE staff with the Vital Records Section and shares the outsourced customer service call center with Public Health's Office of Emergency Preparedness and Response.

In this section of the report, we examine whether Public Health is charging a reasonable fee to patients and whether it has adequate controls over its expenses to ensure that all of its expenses are appropriate. Overall, we found problems with both Public Health's fee setting and its controls over expenses, which we discuss in the final two sections of the report.

Fee Setting

In general, a government fee should be set at a level that is related to the cost of providing the government service being supported by the fee. Setting fees this way ensures government entities cover the costs of providing their services without overcharging those subject to the fees. In addition, the Medical Marijuana Cash Fund is subject to the statutory limit on uncommitted reserves in administrative agency cash funds as set forth in Section 24-75-402(3)(c), C.R.S., which limits the allowed amount of uncommitted cash reserves to 16.5 percent of the total expenses in the fund during the fiscal year. This amount is roughly equal to a 2-month spending reserve and is designed as a control to ensure that government agencies do not collect more in fees than is needed. If a fund's uncommitted reserve balance exceeds the applicable statutory limit, the agency responsible for the fund is required to reduce fees accordingly.

Amendment 20 gave Public Health the authority to levy "reasonable fees" to pay for any direct or indirect administrative costs associated with its role in the State's medical marijuana program [Colorado Const., art. XVIII, sec. 14(3)(i)]. Public Health charges an annual application fee, which is approved by the Board of Health and put into rules, for individuals seeking to obtain or renew a red card. The table below shows the application fee amounts from the Registry's inception in 2001 to the present.

Annual Application Fee for New and Renewal Red Cards June 2001 to Present	
Jun 2001 – May 2007	\$110
Jun 2007 – Dec 2011	\$90
Jan 2012 – Present	\$35
Source: Office of the State Auditor's analysis of information provided by the Department of Public Health and Environment.	

We reviewed fees charged by the Registry, the year-end fund balances for the Medical Marijuana Cash Fund, the fee analyses conducted by Public Health over the past 5 years, and Public Health's budget request documents. We analyzed the average, per-unit cost of processing red cards during Fiscal Years 2010 through 2012 and compared those average direct and indirect costs with the application fees charged to patients during that period. Overall, we found that Public Health has set its application fee too high. As a result, the cash fund balance has grown to a level that far exceeds the program's needs and the uncommitted reserve limit established in statute. We discuss these issues below.

Application fees are set too high. We divided the total annual expenses incurred by the Registry by the total number of red card applications processed annually to determine the average per-card cost of processing red card applications. We found that the Registry incurred direct and indirect costs of between \$12 and \$21 per red card processed during Fiscal Years 2010 through 2012. However, the application fees charged significantly exceeded these costs, as shown in the table below.

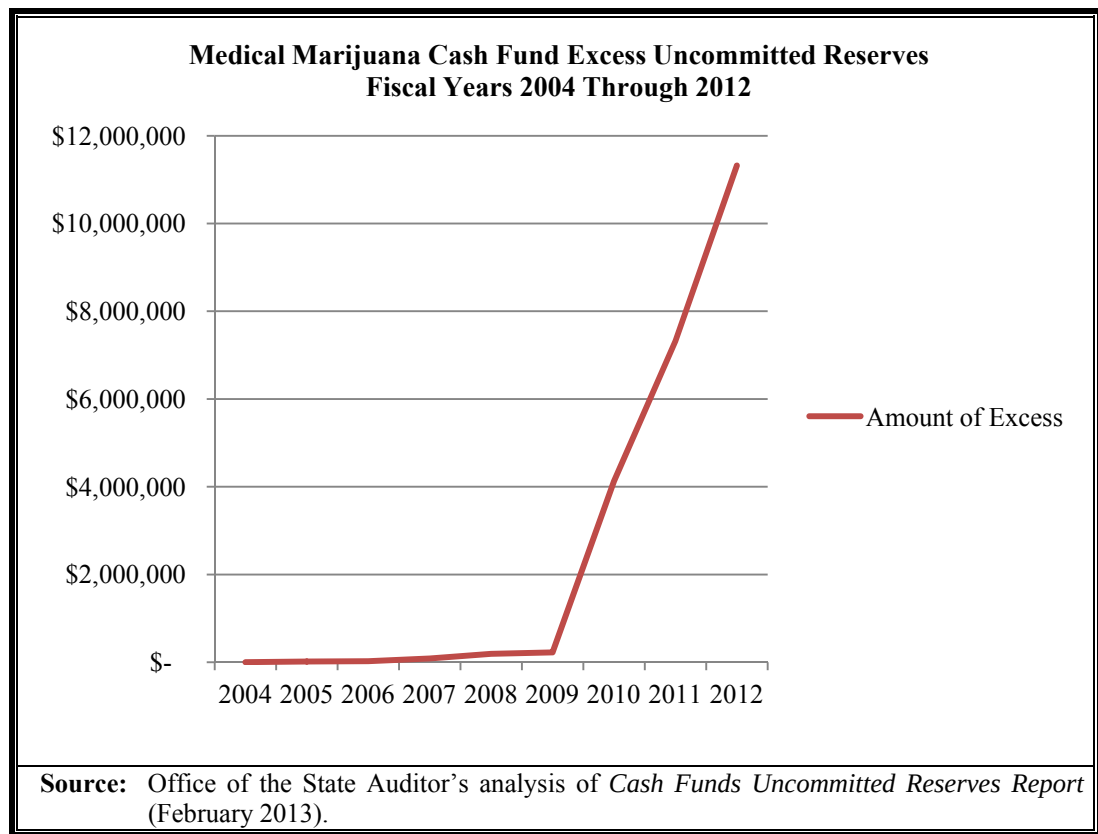
Analysis of the Medical Marijuana Registry's Average Costs to Process Red Cards and Fees Charged to Patients Fiscal Years 2010 ¹ Through 2012			
	2010	2011	2012
Expenses	\$1,050,000	\$2,520,000 ²	\$2,630,000
Number of Applications Processed	91,000	118,000	124,000
Average Cost Per Application Processed	\$12	\$21	\$21
Fee Charged	\$90	\$90	\$90
			\$35 ³
Fee Charged as a Percent of Actual Cost Per Unit	750%	429%	429%
			167% ³
Source: Office of the State Auditor's analysis of data from the Colorado Financial Reporting System and of data provided by the Department of Public Health and Environment.			
¹ Detailed information about the number of cards processed by the Medical Marijuana Registry is only available starting in Fiscal Year 2010.			
² Total excludes \$3 million transfer to the General Fund enacted by House Bill 10-1388.			
³ The fee was lowered to \$35 effective January 1, 2012.			

Because application fees have been set higher than the per-unit cost associated with processing a card, the Registry has brought in significantly more revenue than Public Health needed each year to process red card applications. As shown in the table below, the revenue collected has far outpaced expenses, particularly in the past 3 fiscal years.

Medical Marijuana Cash Fund Revenue, Expenses, and Fund Balance Fiscal Years 2008 Through 2012					
	2008	2009	2010	2011	2012
Revenue	\$253,000	\$783,000	\$4,670,000	\$9,848,000	\$6,414,000
Expenses	138,000	689,000 ¹	1,049,000	5,520,000 ²	2,630,000
Revenue as a Percent of Expenses	183%	182%	445%	392%	244%
Year-End Cash Fund Balance	\$207,000	\$301,000	\$3,922,000	\$8,250,000	\$12,034,000
Source: Office of the State Auditor's analysis of data from the Colorado Financial Reporting System. ¹ Includes a \$259,000 transfer to the General Fund enacted by Senate Bill 09-208. ² Includes a \$3 million transfer to the General Fund enacted by House Bill 10-1388 and a \$5,000 transfer to the Department of Regulatory Agencies authorized by Senate Bill 10-109.					

Based on Public Health's Fiscal Year 2014 budget request documents submitted to the Joint Budget Committee, Public Health foresees the fund balance further growing to \$15 million by the end of Fiscal Year 2014.

Cash fund uncommitted reserve exceeds statutory limits. The State Auditor annually reports on state agencies' compliance with the statutory limit on uncommitted reserves in their cash funds. The most recent *Cash Funds Uncommitted Reserves Report* (February 2013) found that the Medical Marijuana Cash Fund has been out of compliance with the statutory limit every year since Fiscal Year 2004 and had excess uncommitted reserves of more than \$11.3 million at the end of Fiscal Year 2012, the highest amount of excess uncommitted reserve of any cash fund in the State subject to the requirement. As shown in the chart below, the amount of excess uncommitted reserves for this cash fund has grown sharply over the past 3 years.



The dramatically increasing fund balance demonstrates that the application fee charged to patients has not been reasonable because it has far outpaced Public Health's direct and indirect per-card costs associated with administering and monitoring the program. In short, patients have been paying more in application fees than they should have been paying. This situation was created because Public Health has inadequate processes for managing the Registry application fee and cash fund balance. Specifically, Public Health has not analyzed the fee annually and made timely modifications to the fee as necessary, nor included in its fee analyses the cash fund's existing excess reserve balance. We discuss these issues below.

Fee not analyzed and adjusted annually. Rules require Public Health to annually review its fees and to recommend any modification to the fee rate to the Board of Health. We found evidence of two fee analyses completed by staff, one in March 2009 and one in March 2011. However, we did not find that fee analyses were conducted annually, which is particularly concerning given the dramatic increase in demand the Registry has experienced in the past several years.

Additionally, we found a delayed response in reacting to the findings of the fee analyses completed in March 2009 and March 2011. Specifically, in March 2009

staff concluded that the program could lower the fee from \$90 to \$80, but this lower fee was never implemented. Public Health reported that it did not want to change the fee because they were unsure whether the number of people applying for red cards would continue to increase. In March 2011, staff recommended lowering the fee to \$35 for Fiscal Year 2012, but this recommendation was not brought to the Board of Health until September 2011, which was 6 months after the analysis was done, and the fee change was not implemented until January 2012, halfway into the fiscal year. Public Health collected almost twice as much revenue in Fiscal Year 2012 as it had planned for.

Excess reserve not considered in fee analyses. The March 2009 and March 2011 analyses did not consider the existing excess reserves in the Medical Marijuana Cash Fund. For example, the excess reserves at the end of Fiscal Year 2008 were approximately \$190,000, which was about half of the total costs staff expected to have for Fiscal Year 2010 (\$407,000). Staff recommended a fee of \$80, but if they had considered the excess reserves that already existed, we concluded that they would have recommended a fee closer to \$40. For the fee analysis conducted in March 2011, omitting the existing excess fund balance from the equation had an even greater impact for the analysis of what fees were needed for Fiscal Year 2012. By the end of Fiscal Year 2010, the excess reserve topped \$4 million, which was more than Public Health staff was proposing in costs for Fiscal Year 2012; Public Health could have proposed a fee of \$0 and still covered all of its costs in Fiscal Year 2012.

Plans not developed for reducing excess reserves. Staff reported that they do not consider the excess reserve balance when analyzing fees because they try to make sure revenue and expenses balance out each year and believe that existing excess fund balances are not their responsibility to manage but rather should be addressed by policy makers. However, statute clearly makes an agency responsible for managing its cash fund [Section 24-75-402(3)(c), C.R.S.]. Departments annually report via their annual budget request documents submitted to the Joint Budget Committee what their plans are for reducing any excess reserves in their cash funds. For the Fiscal Year 2014 budget request, Public Health reported that the fund balance was expected to increase by about \$1.5 million during Fiscal Year 2014 for a year-end fund balance of more than \$15 million. However, Public Health reported in its budget request documents that it “has no plan for the fund balance.”

With an excess reserve of more than \$11 million at the end of Fiscal Year 2012 and a fund balance expected to grow to \$15 million by the end of Fiscal Year 2014, Public Health needs to take action to ensure that patients are not charged more than necessary and that the fund comes into compliance with statutory limits on excess reserves. First, Public Health should suspend or reduce the fee charged to patients. Second, given how large the excess reserve currently is, Public Health may decide to engage stakeholders on whether the excess reserve should be

addressed by fee suspension alone or by a combination of fee reduction and transfer of funds to another fund or program. We have outlined these two approaches for Public Health to take in addressing the high fees and lowering the excess reserve balance.

Suspend or reduce the application fee. As stated, Public Health should reduce the Medical Marijuana Cash Fund balance by suspending or reducing its Registry application fee, using the excess funds in the cash fund to pay for its direct and indirect costs until the fund balance comes into compliance with the statutory limit on uncommitted reserves. This action would be consistent with the statutory requirement that an agency reduce its fees when an excess cash fund balance occurs [Section 24-75-402(3)(c), C.R.S.]. Based on current patient and expense levels, we estimate that Public Health could stop charging application fees and not run out of funds for 4 fiscal years.

Suspending or reducing the Registry application fee would ensure that the funds are used only for the benefit of the population of people who paid into the fund. In addition, not charging any fee may reduce some costs of administering the program because staff would not have to collect payment and review tax documents submitted by patients seeking the indigent waiver. Finally, this approach could allow Public Health to observe the trends in demand by patients for placement on the Registry as recreational marijuana becomes available for purchase starting in January 2014. As previously discussed, it is unclear whether adult patients aged 21 and older will opt not to be placed on the Registry and instead purchase marijuana through recreational retailers. Public Health could use the time during which the application fee is suspended to observe how the demand for red cards changes in an environment where anyone aged 21 or older can purchase marijuana without a red card. Public Health would then be well positioned to better project ongoing red card demand and resume an appropriate fee to cover its expenses while not creating an excess uncommitted reserve in its cash fund.

Seek legislation to transfer excess reserve funds. An additional option is for Public Health to work with stakeholders in seeking legislation to transfer all or some of the excess reserve funds to another program. Stakeholders and policymakers may decide that the excess reserves would be best put to use for other programs or purposes. For example, Senate Bill 09-208 transferred about \$260,000 and House Bill 10-1388 transferred \$3 million from the Medical Marijuana Cash Fund to the General Fund as part of budget packages recommended by the Joint Budget Committee. There have also been attempts to transfer money from the Medical Marijuana Cash Fund in the last two legislative sessions. House Bill 12-1358, which did not receive a third reading in the Senate before the 2012 session ended, would have transferred up to \$7.7 million to the Department of Revenue for medical marijuana business licensing and enforcement in Fiscal Years 2012 through 2015. House Bill 13-1238 as

introduced would have transferred a total of \$10 million to the Department of Human Services over 4 years for marijuana and prescription drug abuse treatment and for youth prevention services; the provision to transfer funds was struck in committee as the bill sponsor introduced new language to focus the bill on decoupling state and local marijuana business licensing. Any transfers of funds from the Medical Marijuana Cash Fund require legislation because statute as currently written prohibits funds to be transferred from the Medical Marijuana Cash Fund to the General Fund or any other fund [Section 25-1.5-106(17), C.R.S.].

Recommendation No. 8:

The Department of Public Health and Environment should improve its management of the Medical Marijuana Cash Fund (Cash Fund) by:

- a. Suspending or reducing the Medical Marijuana Registry application fee until the Cash Fund's excess reserve balance is in compliance with reserve requirements in Section 24-75-402, C.R.S.
- b. Developing a proposal for further reducing the Cash Fund's excess reserve balance and to include the proposal in its Fiscal Year 2015 budget request submitted to the Joint Budget Committee, and working with the General Assembly as needed to implement the proposal.
- c. Developing policies and procedures for annually reviewing the reasonableness of the Medical Marijuana Registry application fee, including in the analysis any excess reserves in the Medical Marijuana Cash Fund, and making timely recommendations for fee modifications to the Board of Health to ensure the fund balance remains within statutory limits based on the results of the annual analysis.

Department of Public Health and Environment Response:

- a. Agree. Implementation date: January 2014.

The Department will go to the Board of Health to request a hearing to adjust or suspend the fee to reduce the excess reserve balance.

- b. Agree. Implementation date: October 2013.

The Department will seek an opinion from the Attorney General's Office on the appropriate uses of the fund balance. Based on this

opinion, the Department will develop a proposal for reducing the Medical Marijuana Cash Fund's excess reserve balance.

- c. Agree. Implementation date: December 2013.

The Department will develop policies and procedures for annually reviewing the reasonableness of the Medical Marijuana Registry application fee, including in the analysis any excess reserves in the Medical Marijuana Cash Fund, and making timely recommendations for fee modifications to the Board of Health to ensure the fund balance remains within statutory limits based on the results of the annual analysis.

Controls Over Expenses

Statute (Section 24-17-102, C.R.S.) requires state agencies to have internal accounting and administrative control systems that provide for adequate authorization and recordkeeping procedures to ensure effective control over state expenses. State Fiscal Rules generally require (1) expenses to be properly approved and appropriately allocated among the applicable funding sources and (2) any contracts to clearly outline the scope of work, performance period, and payment terms. In addition, one of the Registry's major expenses is outsourced labor through a temporary employment agency and contracted customer service call center. Statute allows for the use of private contractors for personal services in certain circumstances to ensure the efficiency of government services (Section 24-50-501, et seq., C.R.S.), and State Personnel Rules require that an agency complete an analysis and certification outlining the business need for the use of outsourced labor and evaluate the potential impact on the state personnel system to avoid the displacement of state employees.

We reviewed a nonstatistical, judgmental sample of 30 expenses from Fiscal Years 2011 and 2012 totaling \$210,000, or 4 percent of the approximately \$5.1 million spent over that period, to ensure that the expenses complied with State Fiscal Rules and State Personnel Rules. We chose a judgmental sample to ensure that some of the Registry's outsourced labor and contract expenses were included in our testing. From our review of 30 expenses, we identified 13 (43 percent) expenses for which controls were inadequate, representing about \$38,000 (18 percent) of the dollars sampled. The problems included the Registry's (1) management of contracts, (2) use of outsourced labor, (3) allocation of shared expenses, (4) approval of expenses, and (5) controls over travel expenses. Some expenses had more than one problem. We discuss the specific issues we indentified below.

Management of contracts. We found evidence of inadequate contract management for three of 30 sampled transactions. One expense totaling \$19,600 was for one month's call center services, provided under contract with the Denver Health and Hospital Authority. As discussed previously, Public Health's contract with Denver Health and Hospital Authority did not include a scope of work, performance period, and payment terms related to services provided to the Registry, and staff of the medical marijuana program did not monitor the contract. In addition, two of our sampled transactions were for services performed by Central Services. As we discussed previously, Public Health did not have a contract with Central Services for Fiscal Year 2012, the time period under which the expenses from our sample were incurred. The lack of a contractual agreement may limit Public Health's ability to enforce acceptable performance.

Use of outsourced labor. We found a lack of adequate documentation to substantiate the appropriateness of using outsourced labor to conduct the Registry's work. Three of our 30 sampled transactions were expenses under personal services contracts, and we found problems with two of these expenses totaling about \$1,400 for two temporary employees used through Express Employment Professionals. Specifically, we found that Public Health did not have complete and accurate certifications for these two temporary employees. The problems we found with the required certifications in these two cases included (1) a lack of required analysis to demonstrate the cost-effectiveness of using outside labor, (2) incorrect information about the extent of the contractors' services (e.g., incorrectly stating that the temporary agency staff would not work on-site at the Registry and would not use the State's equipment), and (3) failing to attest that the acquisition of outsourced services will not directly or indirectly result in the separation or displacement of classified state employees.

Cost allocation. We found a lack of documentation to substantiate the allocation of expenses that were shared between the Medical Marijuana Cash Fund and other funding sources for seven (23 percent) of our 30 sampled transactions, totaling about \$24,000. Examples of these exceptions included four expenses totaling about \$4,200 charged to the Medical Marijuana Cash Fund for membership dues, conference fees, and staff travel related to a professional association of state vital records and public health statistics offices. The Medical Marijuana Cash Fund should not pay any portion of these costs given that the focus of the association is for professionals who process vital records such as birth and death certificates. Public Health acknowledged that charging all of these costs to the Medical Marijuana Cash Fund was an error and that the costs should have been split with the Vital Records Section.

Because of the concerns we saw with the allocation of expenses in our sample, we requested documentation to show the allocation of salary expenses for all five department employees whose salaries are shared between the Medical Marijuana Cash Fund and other sources. These five employees had 15 to 70 percent of their

salaries paid from the Medical Marijuana Cash Fund. Public Health could not provide documentation to substantiate the allocations, such as information from the time-keeping system to show the amount of time each employee spends on Registry activities.

Approvals. We found a lack of adequate controls over approvals for 6 (20 percent) of the 30 expenses tested, totaling about \$34,000. These expenses did not have proper approvals or sufficient documentation to substantiate the appropriateness of the approval. In three cases, there was no evidence that medical marijuana program staff had reviewed and approved the expense paid by the Medical Marijuana Cash Fund. These expenses included one totaling \$19,600 for one month's outsourced call center services and two expenses totaling about \$7,300 for services from Central Services for scanning Registry applications. We would expect that medical marijuana program staff would review and approve the expense to determine the appropriateness of the invoice and that the correct amount was paid from the Medical Marijuana Cash Fund, in accordance with internal control requirements laid out in Section 24-17-102, C.R.S., and Public Health's own policies. In the remaining three cases, we had concerns that Public Health staff approved expenses without sufficient documentation to substantiate the appropriateness of the approval. For example, Public Health reimbursed the Department of Regulatory Affairs a total of \$5,500 for investigations by the Colorado Medical Board of physicians who had patients in the Registry, but Public Health did not have sufficient documentation to substantiate which physicians were investigated to ensure that the expense was limited to five per year, as required by statute.

Controls over staff travel. We found a lack of adequate controls over staff travel. Four of our tested expenses involved reimbursement for staff travel, and we found concerns with all four expenses. These expenses totaled about \$2,200 and included a mileage reimbursement in excess of the actual mileage for a trip, a misallocation among funding sources, and reimbursement for relatively small amounts of questionable expenses, such as a \$120 excess baggage fee.

The problems we identified were a result of a lack of policies and procedures in some cases and of staff not adhering to existing policies and procedures in other cases. Public Health does not have sufficient policies and procedures for the allocation of shared direct expenses. For example, staff reported that, in general, direct expenses that are tied to an employee (such as conference fees) are allocated to the Medical Marijuana Cash Fund based on the time the employee spends on the medical marijuana program. This procedure is not formally documented in policy, and Public Health acknowledged that the procedure was not followed for expenses in our sample. For contract management, the use of outsourced labor, the allocation of salary expenses, and approving expenses, there is sufficient guidance provided in State Fiscal Rules, State Personnel Rules, and department policies; however, staff did not follow all applicable guidance in our

sample of expenses. To reduce the occurrence of staff not adhering to existing policies and procedures, Public Health should ensure that staff who review, approve, and allocate expenses have received appropriate training on the applicable policies and procedures.

Weak controls over expenses increase the risk of public funds not being used in the most effective manner. As an agency that sets its own fees to cover its expenses, it is important for Public Health to have strong controls over Registry expenses to ensure that patients are not charged more than necessary. Additionally, weak controls over the approval of outsourced labor increase the risk of undermining the principles of the state personnel system.

Recommendation No. 9:

The Department of Public Health and Environment should improve its controls over expenses from the Medical Marijuana Cash Fund by:

- a. Developing policies and procedures for the allocation of shared direct expenses.
- b. Following State Fiscal Rules, State Personnel Rules, and department policies and procedures when expending funds.
- c. Ensuring that all staff in a position to review, approve, and allocate expenses have received training on applicable policies and procedures.

Department of Public Health and Environment Response:

- a. Agree. Implementation date: December 2013.

The Department will develop policies and procedures for allocating shared Medical Marijuana Cash Fund expenses.

- b. Agree. Implementation date: July 2013.

The Department will follow state rules and department policies when expending funds and will document those actions at the time of the expense.

- c. Agree. Implementation date: September 2013.

The Department will train those reviewing, approving and allocating expenses on the applicable policies and procedures.

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Appendix

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Appendix A

Office of the State Auditor Summary of Findings Related to the SMART Government Act Medical Marijuana Regulatory System, Part II Department of Public Health and Environment June 2013

The SMART Government Act [Section 2-7-204(5)(a), C.R.S.] requires the State Auditor to annually conduct performance audits of one or more specific programs or services in at least two departments. These audits may include, but are not limited to, the review of:

- The integrity of the department's audited performance measures.
- The accuracy and validity of the department's reported results.
- The overall cost and effectiveness of the audited programs or services in achieving legislative intent and the department's goals.

The performance audit relating to Colorado's medical marijuana regulatory system was selected for focused audit work related to the SMART Government Act. This document outlines our findings related to the integrity and reliability of performance measurement for the Department of Public Health and Environment's (Public Health) medical marijuana program. We have presented our findings as responses to six key questions that can assist legislators and the general public in assessing the value received for the public funds spent by Public Health in administering the program.

What is the purpose of this program/service?

Public Health is responsible for reviewing and approving applications for "red cards" and maintaining a confidential registry (the Registry) of information related to patients who have been issued red cards. Red cards allow individuals whose physicians have diagnosed them with a qualifying medical condition and have recommended the medical use of marijuana to obtain access to medical marijuana.

What are the costs to the taxpayer for this program/service?

In Fiscal Year 2012, patients paid about \$6.3 million in application fees, and the cash fund earned about \$150,000 in interest income. Medical marijuana program expenses in Fiscal Year 2012 were about \$2.6 million.

How does Public Health measure the performance of this program/service?

Public Health's Fiscal Year 2014 SMART Government Act strategic plan includes no performance measure related to the medical marijuana program. Public Health has not otherwise measured the performance of the program, such as through its monthly publication of program statistics published on Public Health's website.

Is Public Health’s approach to performance measurement for this program/service meaningful?

As discussed in Chapter 2 of the report, we recommend that Public Health measure and report on the medical marijuana program’s timeliness in processing red card applications within the constitutionally required 35-day time frame. During our initial testing of data through December 2012, we found that Public Health did not process about 29 percent of valid red cards within the 35-day time frame. At Public Health’s request, we conducted subsequent testing on applications from January 2013 through April 2013 and found that timeliness had improved significantly with 99 percent of applications being processed within the 35-day time frame. Recommendation No. 2 of the report addresses these issues.

Are the data used to measure performance for this program/service reliable?

As discussed in Chapters 2 and 3 of the report, Public Health generally has the information it needs to report on timeliness of application processing and its compliance with the requirement to process applications within 35 days. From the review we were able to complete of non-personally-identifiable processing dates in the Registry, we found that Public Health could improve data input controls to ensure the accuracy of processing dates captured in the database. Recommendation No. 7 of the report addresses this issue. However, we note that our ability to fully assess the reliability of data in the Registry was limited because of the constitutional protections on Registry data, which do not allow the State Auditor to access any personally identifiable data from the Registry.

Is this program/service effective in achieving legislative intent and Public Health’s goals?

This audit raised concerns about the program’s effectiveness in achieving legislative intent for issuing red cards to patients with qualifying medical conditions, protecting confidential data, and setting reasonable fees. Included throughout the report are recommendations to improve oversight over physicians and caregivers, achieve timely processing of applications, better protect confidential data, set fees at a reasonable level, and ensure funds are spent appropriately.

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