Arizona Department of Health Services
Medical Marijuana Program

Department did not timely, consistently, or adequately perform several medical marijuana regulatory activities and misallocated some Medical Marijuana Fund monies

Performance Audit

June 2019
Report 19-107

A Report to the Arizona Legislature

Lindsey A. Perry
Auditor General

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Audit Staff

Dale Chapman, Director
Marc Owen, Manager and Contact Person
Catherine Clark, Manager

Stephanie Grosvenor, Team Leader
Ashley Bjurstrom
Katie Boligitz
Clinton Pullam

Contact Information

Arizona Office of the Auditor General
2910 N. 44th St., Ste. 410
Phoenix, AZ 85018-7271

(602) 553-0333

www.azauditor.gov

MELANIE M. CHESNEY
DEPUTY AUDITOR GENERAL

ARIZONA AUDITOR GENERAL
LINDSEY A. PERRY

JOSEPH D. MOORE
DEPUTY AUDITOR GENERAL

June 25, 2019

Members of the Arizona Legislature

The Honorable Doug Ducey, Governor

Dr. Cara M. Christ, Director
Arizona Department of Health Services

Transmitted herewith is the Auditor General's report, *A Performance Audit of the Arizona Department of Health Services—Medical Marijuana Program*. This report is in response to a September 14, 2016, resolution of the Joint Legislative Audit Committee. The performance audit was conducted as part of the sunset review process prescribed in Arizona Revised Statutes §41-2951 et seq. I am also transmitting within this report a copy of the Report Highlights for this audit to provide a quick summary for your convenience.

As outlined in its response, the Arizona Department of Health Services agrees with most of the findings and plans to implement all but 1 of the recommendations.

My staff and I will be pleased to discuss or clarify items in the report.

Sincerely,

Lindsey Perry, CPA, CFE
Auditor General


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Performance Audit
Report Highlights
June 2019

Arizona Department of Health Services
Medical Marijuana Program

CONCLUSION: In November 2010, the Arizona Medical Marijuana Act (Act) was passed by a voter ballot initiative, which legalized the medical use of marijuana in the State. The Arizona Department of Health Services (Department) regulates the Act through its Medical Marijuana Program (Program) by issuing medical marijuana registry identification cards (cards) to qualified applicants, inspecting medical marijuana dispensaries and cultivation sites (facilities), investigating complaints against facilities, licensing infusion kitchens, and administering the Medical Marijuana Fund (Fund). As of December 2018, there were 116 certified medical marijuana dispensaries operating in Arizona with 90 cultivation sites. According to the Department, during calendar year 2018, there were 198,017 qualifying patients; 2,022 designated caregivers; and 8,179 dispensary agents. We found that the Department did not always timely revoke some registry identification cards, did not timely and consistently inspect facilities or consistently address facility noncompliance, inadequately investigated some complaints, did not inspect infusion kitchens according to Arizona food safety standards, has not formally reviewed its Program fees, and misallocated some Fund monies.

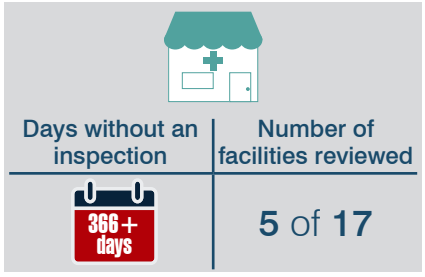
Department should take more timely action to revoke cards

The Department can revoke cards for violations of the Act, such as diverting marijuana to someone not authorized to possess it, or being convicted of an excluded felony offense, such as a violent crime. Our review of 10 cards the Department revoked in fiscal year 2018 found that it took between 21 and 243 working days to revoke them because it did not complete some of the revocation process steps in a timely manner. For example, it took between 1 and 19 working days to request applicable documents describing a cardholder's crime for 4 of the 10 cards reviewed, but took 39 and 42 working days, respectively, for 2 other cards. We found that the Department lacked policies and procedures to help ensure timely revocations.

Recommendation

The Department should develop and implement policies and procedures for revoking cards, including developing and tracking internal steps and associated time frames for revocation process steps.

Some Department medical marijuana regulatory activities not completed timely or consistently, nor adequately performed



Some facility inspections not completed timely or consistently—The Department conducts ongoing inspections of facilities to assess compliance with statutory and rule requirements, such as whether facilities have adequately packaged and labeled medical marijuana. The Department reported that its unwritten goal is to inspect each facility at least once each year. We reviewed a random sample of 10 dispensaries that were in operation as of May 2018, and 7 associated cultivation sites, and found that 5 facilities were not inspected in more than a year at one point throughout their operation. Long delays between inspections may put the public at risk. We also found that the Department inconsistently assessed compliance during inspections, which can affect the Department's ability to effectively monitor a facility's compliance with statutory and rule requirements and can lead to confusion among inspectors and dispensaries. The Department did not formally establish an inspection frequency goal and did not develop adequate facility inspection policies and procedures.

Some complaints inadequately investigated and monitored—We reviewed a random sample of 30 online facility complaints submitted to the Department between August 2015 and May 2018 and found that some complaints were incorrectly determined to not be within the Department's jurisdiction and therefore, were not investigated; some complaints were inaccurately categorized after investigation; and complaint investigations were not adequately documented. Inadequately investigating complaints impacts the Department's ability to effectively protect public health and safety. In addition, we found that the Department's complaint-handling policies and procedures were outdated.

Facility noncompliance not consistently addressed—The Department uses various approaches to address facility noncompliance, including requiring the facility to submit a correction plan and holding "provider meetings" to discuss concerns with the facility. However, our review of 4 substantiated complaints with similar violations found the Department inconsistently addressed these violations. The Department was not able to explain why different actions were taken for these complaints and it did not have policies and procedures specific to addressing facility noncompliance.

Infusion kitchens not inspected as food establishments—As of December 2018, the Department licensed 36 infusion kitchens as food establishments, which prepare marijuana-infused edible food products at facilities. Although Arizona's food safety regulations require ongoing food safety inspections for food establishments, the Department reported that it does not inspect infusion kitchens for ongoing food safety compliance because facilities typically close infusion kitchens on the dates when the Department has announced that it will conduct a medical marijuana inspection. However, food establishments can be inspected for compliance with various food safety requirements, even if food is not being prepared at the time of inspection, including handwashing, coolers or freezers, food preparation sinks, and the temperature of any food or ingredients in the kitchen. The Department's failure to regularly inspect infusion kitchens places qualifying patients at risk of purchasing and consuming food products without adequate oversight to prevent foodborne illnesses.

Recommendations

The Department should develop, or update, and implement policies and procedures for:

- Its inspection processes, including how often inspections should be conducted and how violations will be assessed.
- Its complaint-handling processes, including determining and documenting whether complaints are in its jurisdiction, documenting all complaint investigation activities, and tracking and monitoring all complaints.
- Addressing statutory and rule violations by medical marijuana facilities.

The Department should conduct unannounced food safety inspections of infusion kitchens on an ongoing basis similar to its inspection practices for other licensed food establishments in the State.

Department should establish and implement process for setting Program fees

The Department charges cardholders and facilities initial and renewal fees to pay for Program costs, such as the cost associated with reviewing, processing, and issuing cards. According to the Department, it established its fee amounts in rule in 2011 and has not formally reviewed the appropriateness of the Program's fees since they were initially set. Further, the Department has not conducted a cost analysis of the Program. Without accurate cost information, the Department cannot ensure that its fees are appropriately set, which may result in placing an undue cost burden on Program participants or result in insufficient monies to cover Program costs.

Recommendation

The Department should determine the costs for providing its Medical Marijuana Program and set its fees accordingly.

Department misallocated some Medical Marijuana Fund monies

The Act established the Fund, and the use of Fund monies must benefit the Program. However, our review of fiscal year 2018 Fund expenditures identified some costs that were not proportionally allocated relative to the benefit the Program received. For example, we identified 2 employees with estimated salaries totaling approximately $131,000 that were fully paid by the Fund in fiscal year 2018; however, these 2 employees worked on other programs or responsibilities that were not related to the Program for approximately 15 and 5 percent of their time, respectively. Additionally, we reviewed a judgmental sample of 65 of the 7,177 fiscal year 2018 Fund expenditure transactions, totaling approximately $2.6 million. For 30 of these 65 transactions, totaling approximately $962,000, the Fund paid the full cost of the transaction, but other Department programs also benefited from the expenditures. Overall, the Department did not have documentation supporting how the allocation amounts were determined. We found that the Department had not developed written policies and procedures regarding the use of Fund monies that could assist in determining whether an expenditure is allowable and whether the expenditure should be allocated to the Fund. As of April 2019, the Department reported that it had established a department-wide process for required approvals of expenditures.

Recommendation

The Department should establish and implement written policies and procedures regarding the allowable use of Fund monies and guidance for allocating expenditures when multiple programs benefit from the expenditure.

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INTRODUCTION

The Office of the Auditor General has released the first in a series of 4 performance audit reports of the Arizona Department of Health Services (Department). This performance audit report focuses on the Department's Medical Marijuana Program. The second report focuses on the Department's processes for procuring goods and services through contracts, monitoring contracts and agreements to ensure requirements are met, and processing payments for contracts and agreements. The third report will focus on the Department's administration of the Arizona State Hospital, and the final report will provide responses to the statutory sunset factors.

Department mission

The Department's mission is to promote, protect, and improve the health and wellness of individuals and communities in Arizona. To help fulfill this mission, the Department reported it administers over 300 programs, including the Medical Marijuana Program (Program).

Voters authorized medical use of marijuana in Arizona

In November 2010, the Arizona Medical Marijuana Act (Act) was passed by a voter ballot initiative, which legalized the medical use of marijuana in the State. The Act, which was codified in Arizona Revised Statutes (A.R.S.), provides a regulatory framework for the cultivation, dispensation, and personal consumption of medical marijuana by qualified cardholders and/or dispensaries, including qualifying patients, designated caregivers, and dispensary agents. Because the Act was passed by a voter ballot initiative, it can only be amended if a proposed change furthers the purpose of the Act and passes with a three-fourths vote in the Legislature. In May 2019, the Legislature passed Laws 2019, Ch. 318, which added or modified some provisions of the Act. Many of these changes become effective on the general effective date, August 27, 2019, and are discussed throughout this report.

Department oversees medical marijuana in Arizona

The Department regulates the Act through its Program, which oversees the issuance of medical marijuana registry identification cards; provides some physician oversight; issues certificates to nonprofit medical marijuana dispensaries and cultivation sites (medical

Key terms and definitions

Qualifying patient—a person who has been diagnosed by a physician as having a debilitating medical condition.

Debilitating medical condition—cancer, glaucoma, HIV, AIDS, hepatitis C, amyotrophic lateral sclerosis, Crohn's disease, agitation of Alzheimer's disease, post-traumatic stress disorder, cachexia, severe and chronic pain, nausea, seizures, and muscle spasms.

Designated caregiver—a person who is at least 21 years old and has agreed to assist with a patient's medical use of marijuana. The designated caregiver may acquire, possess, cultivate, transport, and facilitate the patient's consumption of medical marijuana for up to 5 qualifying patients.

Dispensary—a nonprofit entity registered with the Department that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, supplies, sells, or dispenses medical marijuana or related supplies and educational materials to cardholders.

Dispensary agent—a principal officer, board member, employee, or volunteer of a medical marijuana dispensary who is at least 21 years old and has not been convicted of an excluded felony offense.

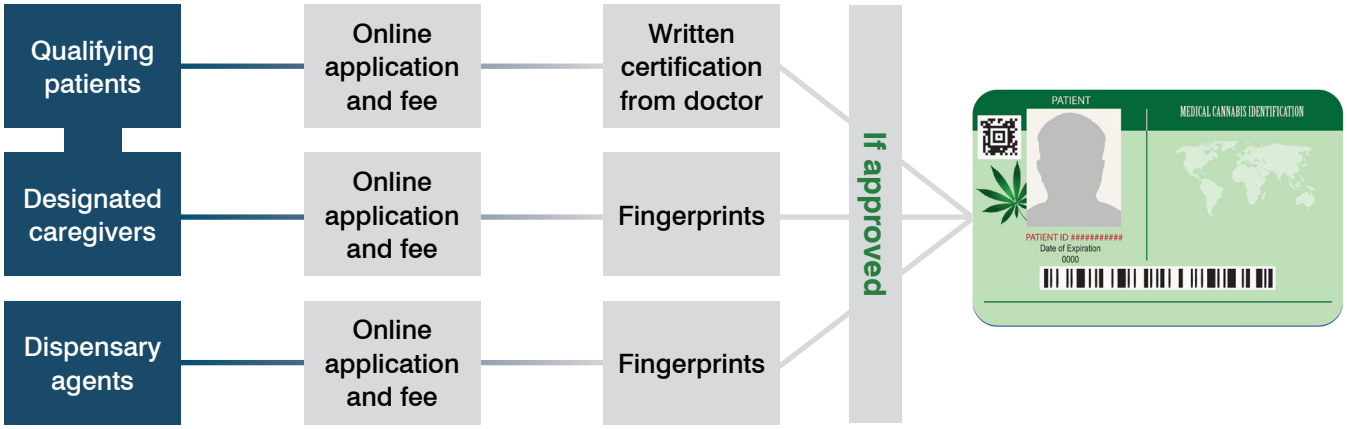
Authorized cultivation—allows the qualifying patient, or the designated caregiver on the qualifying patient's behalf, to cultivate, i.e., grow, marijuana if the qualifying patient lives more than 25 miles from a certified dispensary. Each patient can have 12 marijuana plants contained in an enclosed, locked facility.

Source: A.R.S. §§36-2801, 36-2804, and 36-2804.02.

marijuana facilities); inspects medical marijuana facilities; and administers the Medical Marijuana Fund (Fund). Specifically:

Department issues medical marijuana registry identification cards—The Department issues registry identification cards (cards) to qualifying patients, designated caregivers, and dispensary agents.[1] As illustrated in Figure 1, to receive a card, applicants must complete an online application, which includes demographic information, such as name, date of birth, and residential address; provide a physician's written certification form specifying the debilitating medical condition, if applying for a qualifying patient card, or fingerprints for a criminal history background check if applying for a designated caregiver or dispensary agent card; and submit the application fee.[2,3] All registry identification cards are valid for 1 year, after which the cardholder must resubmit the required documentation and application fee to the Department to renew their card.[4,5] Statute allows qualifying patients to obtain 2.5 ounces of medical marijuana per 14-day period.[6] Prior to dispensing marijuana, a dispensary must use the Department's online verification system to confirm that the qualifying patient or designated caregiver has a valid card, enter the marijuana amount dispensed, and verify that the purchase would not cause the qualifying patient to exceed the 2.5-ounce limit.[7]

Figure 1
Cardholder application requirements



Source: Auditor General staff analysis of A.R.S. §§36-2804.02, 36-2819, and Arizona Administrative Code (AAC) R9-17-103.

The number of qualifying patient cardholders and the amount of marijuana sold has increased since the Program began (see Figure 2, page 3). According to the Department, during calendar year 2018, there were 198,017 qualifying patients; 2,022 designated caregivers; and 8,179 dispensary agents.[8] Further, according to the Department, 121,916 pounds of medical marijuana were sold to qualifying patients and designated caregivers in calendar year 2018.

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1 Laws 2019, Ch. 318, added independent third-party laboratory agents as a new cardholder type. These cardholders will work in independent third-party laboratories to test medical marijuana, a new requirement also added by Laws 2019, Ch. 318. Laboratory agents must meet the same requirements as dispensary agents. Laws 2019, Ch. 318, becomes effective on August 27, 2019, although medical marijuana testing is not required until November 2020.

2 The written certification form must be dated within 90 days preceding the date of application and supplied by a licensed homeopathic doctor, medical doctor, naturopathic doctor, or osteopathic doctor.

3 A.R.S. §§36-2804.02 and 36-2819.

4 A.R.S. §36-2804.06 and AAC R9-17-204.

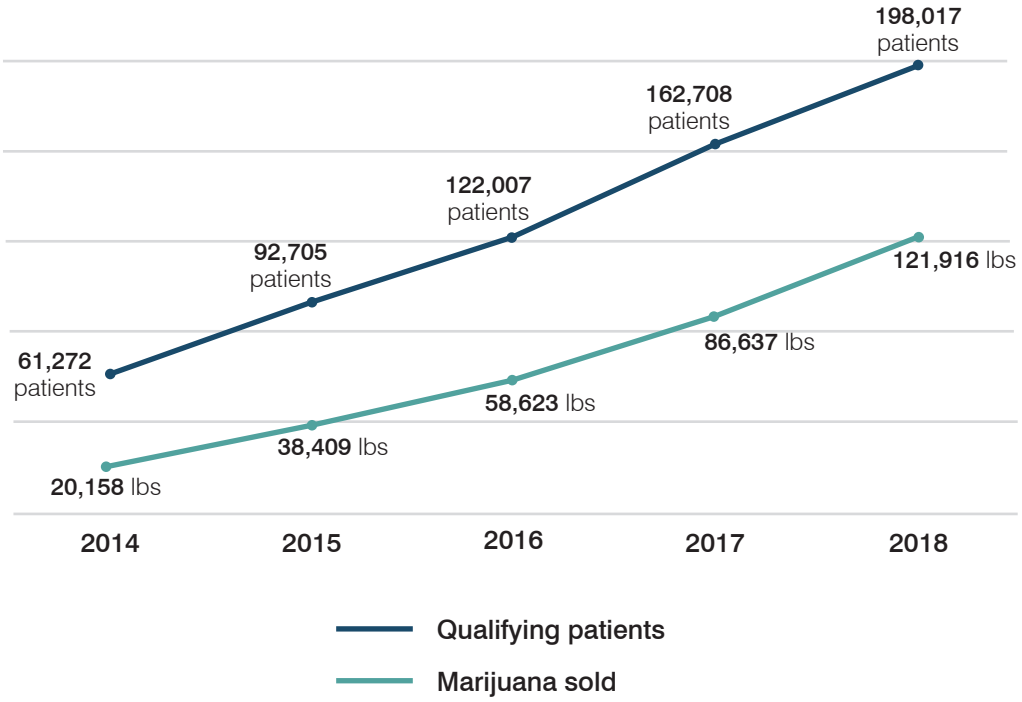
5 Laws 2019, Ch. 318, changed the length of time a card is valid from 1 year to 2 years. This change becomes effective on August 27, 2019.

6 A.R.S. §36-2806.02.

7 The Department's online verification system shows all transactions made during the past 60 days by qualifying patients or their designated caregiver along with the amount purchased in the past 14 days.

8 During calendar year 2018, 2,613 qualifying patients and designated caregivers were authorized to cultivate medical marijuana.

Figure 2
Cumulative number of qualifying patients and amount of marijuana sold (pounds)
Calendar years 2014 through 2018
(Unaudited)



Source: Auditor General staff summary of the Department's Medical Marijuana Program End of Year Reports for calendar years 2014 through 2018.

We reviewed a random sample of 30 qualifying patient, 10 designated caregiver, and 10 dispensary agent registry identification cardholder applications from fiscal year 2018 and found that the Department issued these 50 cards in a timely manner and in accordance with statutory and rule requirements (see textbox).[9] We also reviewed a random sample of 5 qualifying patient applications and 5 dispensary agent applications that were denied in fiscal year 2018 and found that the Department denied the 10 applications for appropriate reasons.[10] In most cases, applicants were denied a card because of incomplete or inaccurate applications.

Department provides some physician oversight—Although neither statute nor rule addresses the Department's responsibility or authority for overseeing physicians, the Department has implemented mechanisms to provide some

Examples of statutory and rule requirements for cardholders

Qualifying patients
- Copy of identification.
- Current photo.
- Written certification form issued by a physician within the 90 days immediately preceding the date of the application that specifies the qualifying patient's debilitating medical condition.
- Signed statement pledging not to divert marijuana to anyone who is not allowed to possess it.

Designated caregivers and dispensary agents
- Copy of identification.
- Current photo.
- Signed statement that they have not been convicted of an excluded felony offense.
- Full set of fingerprints submitted to the Department for the purpose of obtaining a State and federal criminal history background check.

Source: Auditor General staff review of A.R.S. §§36-2801, 36-2804.01, and 36-2804.02; and AAC R9-17-202 and R9-17-311.

[9] We selected the random sample from the population of active cardholders as of June 30, 2018, which consisted of 172,227 qualifying patients, 913 designated caregivers, and 5,261 dispensary agents.

[10] According to the Department, it denied 49 qualifying patient applications and 33 dispensary agent applications in fiscal year 2018, but did not deny any designated caregiver applications.

physician oversight. Specifically, the Department works with the Arizona State Board of Pharmacy (Pharmacy Board) to check the number of times a certifying physician—one who recommended medical marijuana to a patient—checked the Controlled Substances Prescription Monitoring Program (CSPMP) database within a 6-month period. The CSPMP is a central database managed by the Pharmacy Board that is used to track the prescribing, dispensing, and consumption of controlled substances. As part of completing certifications for medical marijuana, rule requires the certifying physician to attest that he/she has checked the CSPMP database for each qualifying patient.[11] Certifying physicians are required to check the CSPMP to review the medications the patient has used in the past and may currently be prescribed and taking. The Department has established a process to provide information to the appropriate physician regulatory board (Homeopathic, Medical, Naturopathic, or Osteopathic) to further investigate and take action, as appropriate, if it determines that the certifying physician may not have checked the CSPMP for each certification. For example, the Arizona Medical Board reported that it received notifications from the Department regarding 6 physicians in October 2018 and, as of December 2018, was investigating 5 of these physicians and had administratively closed the remaining case because the physician had already surrendered his license.

Additionally, rule requires each dispensary to have a physician serve as its medical director.[12] The medical director is responsible for providing training to dispensary agents so they can provide information to qualifying patients and designated caregivers, such as the risks and benefits of medical marijuana, and to help recognize signs and symptoms of substance abuse. Rule also states that a medical director cannot provide a written certification for any qualifying patient.[13] According to Department staff, they perform a quarterly comparison of certifying physicians and active medical directors to identify any potential instances of a medical director who is also acting as a certifying physician and reported that they have not identified any such instances.

Department issues registration certificates to medical marijuana dispensaries—To legally operate in the State, a dispensary must have a dispensary registration certificate (DRC). The Department grants DRCs through an allocation process (see Figure 3 on page 5). To obtain a DRC, an applicant must complete an application form and meet all statutory and rule requirements. In assessing whether an applicant meets statutory and rule requirements, the Department conducts an administrative and substantive review of DRC applications. The Department's administrative review assesses whether an applicant submitted all required application documentation, such as policies and procedures for security and a copy of a dispensary's bylaws. If an application is determined to be administratively complete, the Department assesses substantive completeness by reviewing items such as whether the applicant's security policies and procedures address restricting access to areas of a dispensary or cultivation site that contain marijuana and assessing whether the dispensary's bylaws indicate whether the dispensary plans to deliver medical marijuana to qualifying patients.

Dispensary registration certificate (DRC)— Authorizes an individual(s) or organization to open a medical marijuana dispensary. A.R.S. §36-2804 limits the number of certificates available to 1 per every 10 pharmacies in the State.

Source: Auditor General staff review of A.R.S. §36-2804.

In making the final allocation determination for applications that are considered both administratively and substantively complete, rule requires the Department to allocate the DRC to the applicant that would serve the most qualifying patients within a 10-mile radius of the proposed location.[14,15] If there is a tie or a margin of 0.1 percent or less based on the number of qualifying patients a prospective dispensary would serve in comparison

[11] AAC R9-17-202(F)(5)(i)(iii).

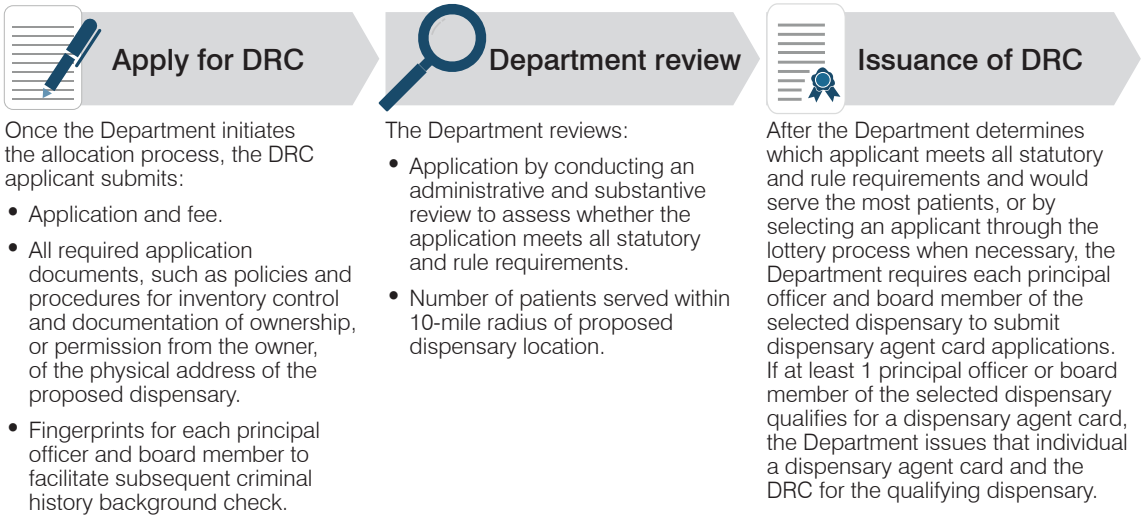
[12] AAC R9-17-310(A)(5).

[13] AAC R9-17-313(E).

[14] A DRC applicant's proposed location corresponds to the geographic boundaries of a specific Community Health Analysis Area (CHAA). CHAAs are geographic areas that were previously established by the Department for use in public health programs. Once a dispensary has a DRC, it can move locations within its CHAA during the first 3 years. After 3 years, the dispensary can move to another location in the State. However, Laws 2019, Ch. 318, modified the criteria that dispensaries certified on or after April 2020 must meet in order to change locations.

[15] Laws 2019, Ch. 318, revised how the Department must prioritize new DRC applications during the allocation process, such as giving a higher priority to applications for geographic areas from where a dispensary has moved. These changes become effective in April 2020.

Figure 3
DRC application and allocation process



Source: Auditor General staff review of A.R.S. §36-2804, AAC R9-17-107, R9-17-303, and R9-17-304; Department documents; and interviews with Department staff.

to other applicants, the Department uses a lottery process to allocate the DRC. The Department has initiated the DRC allocation process twice, once in 2012 and again in 2016.[16] In 2016, the Department received 750 DRC applications and issued 31 DRCs, 9 of which were issued using the lottery process.[17]

We judgmentally selected and reviewed the applications of 6 DRC applicants from the 2016 allocation, 5 of which were allocated a DRC. We reviewed the application materials against the requirements in statute and rule to determine if the Department appropriately deemed the applications administratively and substantively complete. We found that the Department appropriately deemed the 5 applications administratively and substantively complete when allocating DRCs to these 5 applicants. The sixth application we reviewed was withdrawn by the applicant during the Department's administrative review.

In addition, the Department used a Geographic Information System (GIS) mapping contractor to map the locations of prospective dispensaries, qualifying patients, and operating dispensaries within a 10-mile radius to determine which prospective dispensaries would serve the most qualifying patients. We found that the GIS mapping contractor's calculations were appropriate for the 6 DRC applications we reviewed.

Department provides oversight of dispensaries and cultivation sites—After receiving a DRC, a dispensary must apply for and receive an approval to operate (ATO) certificate to open and operate a dispensary or cultivation site.[18] Prior to issuing an ATO certificate, the Department conducts an initial inspection to assess whether the dispensary or cultivation site complies with statutory and rule requirements, such as checking that educational materials for qualifying patients include information on any alternative medical options and potential side effects, security cameras cover all entrances and exits from the building, and product labels list the date of harvest and all chemical additives. As of December 2018, there were 116 certified medical marijuana dispensaries operating in Arizona with 90 cultivation sites.[19]

[16] AAC R9-17-303 states that each calendar year, the Department shall review the number of DRCs and determine if any certificates are available to allocate. According to Department officials, they contact the Pharmacy Board on a quarterly basis regarding how many licensed pharmacies are in the State to determine whether it can issue additional DRCs. However, rule does not specify a frequency for allocating DRCs.

[17] The Department contracted with an accounting firm to administer the lottery process.

[18] A dispensary can have 1 cultivation site at the same location as its dispensary and 1 additional cultivation site at an offsite location. A dispensary and its cultivation site(s) operate under the same DRC, but the Department requires them to have separate ATO certificates.

[19] Because a dispensary can, according to rule, obtain medical marijuana from another dispensary or another dispensary's cultivation site, or a qualifying patient or designated caregiver that is authorized to cultivate medical marijuana, not all dispensaries need to have a proprietary cultivation site.

Once a medical marijuana facility has an ATO certificate and is operating, the Department conducts ongoing inspections to check for compliance with statutory and rule requirements (see Finding 2, pages 13 through 16, for more information on inspections), including inspections that may result from complaints (see Finding 3, pages 17 through 20, for more information on complaints).[20] Additionally, the Department issues food establishment licenses for kitchens at dispensaries or cultivation sites that prepare marijuana-infused edible food products for qualifying patients (see Finding 5, pages 25 through 26, for more information on infusion kitchens).[21] Finally, Laws 2019, Ch. 318, requires the Department to regulate and certify independent third-party laboratories (labs) to test medical marijuana starting in November 2020. The regulatory framework for labs is similar to dispensaries, such as the labs being subject to reasonable inspection by the Department.

Statute also requires dispensaries to operate on a not-for-profit basis but does not require them to be recognized as tax-exempt by the federal Internal Revenue Service.[22] Rule requires dispensaries to submit a copy of an annual financial statement for the previous year, along with a financial statement audit prepared by an independent certified public accountant.[23]

Program information is confidential by law

According to statute, the information the Department collects to administer the Program is confidential and not subject to disclosure or inclusion in any other list or database.[24,25] This confidential information includes the individual names and identifying information of cardholders; information regarding a qualifying patient's designated caregiver or physician; the physical addresses of the dispensaries; and the contents and supporting documents provided during the application or renewal process by the qualifying patients, designated caregivers, dispensary agents, and dispensaries.

Budget and funding

The Act also established the Medical Marijuana Fund (Fund), which may consist of any fees collected, civil penalties imposed, and private donations received as part of regulating medical marijuana.[26] As shown in Table 1 on page 7, the Program's revenues were approximately $16.6 million in fiscal year 2016 and are estimated to increase to approximately $30.1 million for fiscal year 2019. Revenues are from licenses and fees (see Finding 6, pages 27 through 29, for more information about fees). The Fund's fund balance was approximately $11.6 million beginning in fiscal year 2016 and is estimated to increase to approximately $63.3 million at the end of fiscal year 2019.

The Program had expenditures and transfers out totaling approximately $8.3 million in fiscal year 2016 and are estimated to be approximately $16.4 million for fiscal year 2019. The largest source of expenditures was other operating costs, totaling approximately $5.1 million in fiscal year 2018, and is estimated to increase to approximately $8.3 million in fiscal year 2019. The Department's other operating costs comprised external

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[20] The Department also conducts inspections if a medical marijuana dispensary wants to move the location of its dispensary or cultivation site, or if it wants to make modifications to a facility, such as structural modifications that result in an expansion of the existing approved area.

[21] In May 2019, the Arizona Supreme Court ruled that medical-marijuana extracts, such as oils that are commonly used for edible food products, are protected under the Act.

[22] A.R.S. §36-2806.

[23] AAC R9-17-308.

[24] A.R.S. §36-2810.

[25] Laws 2019, Ch. 318, modified the confidentiality restrictions to exempt data that is used for public health research. This change becomes effective on August 27, 2019.

[26] The Department is authorized to impose civil penalties if cardholders fail to comply with specific statutory requirements. For example, if a qualifying patient, designated caregiver, or dispensary agent fails to notify the Department of a name or address change within 10 days, the Department can impose a civil penalty up to $150. Additionally, Laws 2019, Ch. 318, effective August 27, 2019, authorizes the Department to assess civil penalties on cardholders and facilities of up to $1,000 per day per violation of statute and rule, up to $5,000 for a 30-day period, and requires the Department to consider certain criteria, such as repeated violations, the type and severity of violations, and the potential for harm, when determining the penalty amount.

Table 1
Medical Marijuana Fund's schedule of revenues, expenditures, and changes in fund balance
Fiscal years 2016 through 2019
(Unaudited)

	2016 (Actual)	2017 (Actual)	2018 (Actual)	2019 (Estimate)
Revenues				
Licenses and fees	$16,865,920	$25,295,865	$29,127,700	$30,395,783
Credit card fees	(295,265)	(453,931)	(551,987)	(256,092)
Total revenues	**16,570,655**	**24,841,934**	**28,575,713**	**30,139,691**
Expenditures and operating transfers out				
Payroll and related benefits	1,735,065	1,989,440	2,202,861	2,569,061
Professional and outside services[1]	1,402,792	1,740,693	1,797,403	2,114,302
Contract payments[2]	2,268,627	2,910,942	1,423,959	2,200,000
Travel	47,108	47,587	35,891	69,000
Other operating[3]	2,192,763	3,881,717	5,068,219	8,284,000
Furniture, equipment, and software	44,253	222,492	489,387	300,000
Total expenditures	7,690,608	10,792,871	11,017,720	15,536,363
Operating transfers out[4]	604,260	861,599	990,867	891,854
Total expenditures and operating transfers out	**8,294,868**	**11,654,470**	**12,008,587**	**16,428,217**
Net change in fund balance	8,275,787	13,187,464	16,567,126	13,711,474
Fund balance, beginning of year	11,598,865	19,874,652	33,062,116	49,629,242
Fund balance, end of year	**$19,874,652**	**$33,062,116**	**$49,629,242**	**$63,340,716**

1 Most of the professional and outside services comprised legal services.

2 Amounts represent payments to entities the Department contracts with for various projects. Nearly 80 percent of the contract payments are to the University of Arizona for various services including reviewing and evaluating medical marijuana data.

3 Other operating expenditures comprised various expenditures such as external programming, software support and maintenance, fingerprint/background checks, and supplies. According to the Department, the amount has increased between fiscal years 2016 and 2019 because the Program has grown over these fiscal years with an increased number of qualifying patients (see Figure 2 on page 3). In addition, the Program has incurred increasing information technology costs, such as developing a new cardholder licensing system and paying an access fee for the State's CSPMP database beginning in fiscal year 2017 (see page 32 for additional information). In addition, according to a March 2018 agreement, the Department pays $2 million annually to the Arizona Department of Revenue to provide information to licensed medical marijuana dispensaries on the accurate and timely submission of Arizona taxes and to perform various other services, such as tax collections and audits.

4 Operating transfers out primarily consist of monies transferred to the Department for the Fund's share of administrative personnel and overhead costs.

Source: Auditor General staff analysis of the Arizona Financial Information System (AFIS) *Accounting Event Transaction File* and the *State of Arizona Annual Financial Report* for fiscal years 2016 through 2018; and Department-provided financial information for fiscal year 2019.

computer programming, software support, fingerprint/background checks, and office supplies. Because the Act was passed by voter initiative, the monies from the Fund are protected and must be used for purposes benefiting the Program (see Finding 7, pages 31 through 34, for more information on the Fund).

Department should take more timely action to revoke registry identification cards

Department authorized to revoke registry identification cards for violations of the Act

As described in the Introduction, the Department issues medical marijuana registry identification cards to qualified applicants who submit the required documentation and meet all statutory and rule requirements. According to statute, the Department can also revoke registry identification cards for violations of the Act, such as diverting marijuana to someone not authorized to possess it and being convicted of an excluded felony offense (see textbox). In fact, statute requires the Department to "immediately revoke" the registry identification card of a dispensary agent convicted of an excluded felony offense.[27] Although designated caregiver and dispensary agent applicants must submit their fingerprints as part of the application process, statute does not require the Department to perform a background check prior to card issuance.[28] Once the application is approved, the Department provides the fingerprints to DPS to conduct a federal and State background check. Generally, the Department first learns that it may need to pursue revocation when it receives the fingerprint criminal history background report.[29]

Excluded felony offense

(a) A violent crime, which includes any criminal act that results in death or physical injury or any criminal use of a deadly weapon or dangerous instrument, that was classified as a felony in the jurisdiction where the person was convicted.

(b) A violation of a state or federal controlled substance law that was classified as a felony in the jurisdiction where the person was convicted but does not include:

- An offense for which the sentence, including any term of probation, incarceration, or supervised release, was completed 10 or more years earlier.
- An offense involving conduct that would be immune from arrest, prosecution, or penalty under the Act except that the conduct occurred before the Act became effective (December 14, 2010) or was prosecuted by an authority other than the State of Arizona.

Source: A.R.S. §36-2801(7).

[27] A.R.S. §36-2815.

[28] According to the Department, it provides fingerprints to the Arizona Department of Public Safety (DPS) to conduct the criminal history background check after issuance 1) to ensure that the applicant has submitted a completed application and is otherwise qualified to receive a card and 2) because of the rule requirement to issue the card within 15 days of receiving an application.

[29] In some cases, a police department may report to the Department that an existing cardholder has been arrested for a marijuana-related offense, such as diverting marijuana to someone not authorized to possess it, in which case the Department may also pursue revocation.

The revocation process encompasses various steps, including:

- **Reviewing the criminal history background report—**After the Department receives the criminal history background report from DPS, it reviews the information and determines whether the cardholder has any convictions that would be considered an excluded felony offense.
- **Requesting additional documentation about a crime—**The criminal history background report alone does not include enough information for the Department to make a determination whether an identified crime meets the definition of an excluded felony offense. For example, the criminal history background report may indicate that an assault was committed, but it may not describe whether it was classified as a violent crime. Therefore, the Department will request additional documentation from the jurisdiction in which the cardholder was arrested or convicted, such as the police report or plea agreement, to determine whether a crime meets the definition of an excluded felony offense.
- **Determining whether revocation is warranted—**After the Department receives the requested documentation, it will hold an internal meeting to discuss its next steps, which may include pursuing revocation or seeking counsel from the Arizona Attorney General's Office on next steps based on the evidence.
- **Informing the cardholder of the impending revocation—**After the Department has determined it must revoke the card, it sends the cardholder a "notice of intent to revoke," which outlines the reason(s) for revocation and informs the cardholder that they have 30 days to file an appeal.[30]
- **Sending a final revocation letter—**If the cardholder does not appeal the notice of intent to revoke during those 30 days, the Department sends a final letter to the former cardholder indicating that his/her card has been revoked.[31]

Department did not always take quick action to revoke some registry identification cards

We judgmentally sampled files for 10 registry identification cardholders who were revoked in fiscal year 2018—3 qualifying patients, 3 designated caregivers, and 4 dispensary agents—and found that the Department appropriately revoked these registry identification cards.[32] The reasons for revocation included violations of the Act, such as selling or facilitating the sale of marijuana as a qualifying patient, and being convicted of an excluded felony offense, including possessing narcotic drugs for sale and aggravated assault.

Although neither statute nor rule identifies a specific overall time frame for revocation, the Department did not consistently take timely action to revoke the 10 registry identification cards we reviewed. Overall, the Department took between 21 and 243 working days to revoke these 10 registry identification cards (see Figure 4, page 11, for total revocation times for the 10 files reviewed).[33] Although the time required for some steps in the revocation process is outside of the Department's control, such as waiting for requested documents from the jurisdiction where the cardholder was arrested or convicted, the Department did not always complete other steps that are within its control in a timely manner. For example, for 4 registry identification cards we reviewed, the Department took between 1 and 19 working days to request applicable documents describing a cardholder's crime after

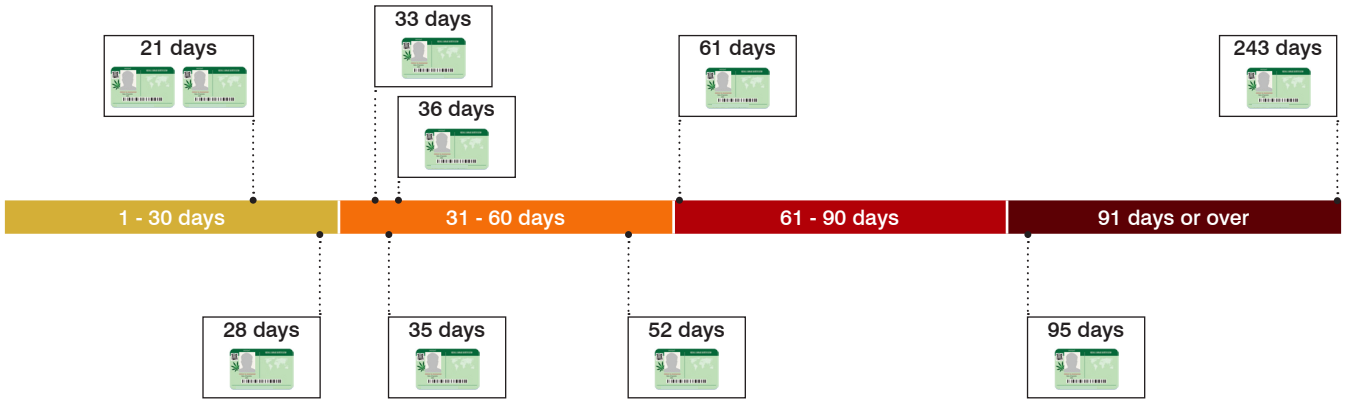
[30] The cardholder may request to appeal the Department's revocation of the registry identification card by requesting a hearing before the Arizona Office of Administrative Hearings (OAH) where an administrative law judge issues a decision as to whether revocation is proper. The Department can accept, reject, or modify OAH's decision, which results in a final administrative decision that the cardholder may further appeal to superior court.

[31] Prior to dispensing marijuana, a dispensary must use the Department's online verification system to confirm that the qualifying patient or designated caregiver has a valid card. Therefore, if a former cardholder tries to buy medical marijuana after his/her card has been revoked, the system would show that the card was revoked.

[32] According to the Department, during calendar year 2018, there were 208,218 registered cardholders. The Department revoked 35 registry identification cards in fiscal year 2018.

[33] The Department was unable to provide dates for all steps of the revocation process for 5 of the 10 registry identification cards reviewed. Therefore, we calculated the total time to revoke a card starting with the earliest date provided by the Department.

Figure 4
Total revocation time for 10 registry identification cards reviewed



Source: Auditor General staff review of 10 registry identification cards revoked in fiscal year 2018.

reviewing the criminal history background report; however, this step took 39 and 42 working days, respectively, for 2 other cards.[34] In addition, the Department took less than 10 days to send the final revocation letter for 5 of the registry identification cards but took 22 days to issue this letter for another card.[35] Department staff reported that they use a spreadsheet or calendar appointments to help remind them when they should prepare and send a final revocation letter. However, the Department did not provide an explanation as to why some revocation process steps within its control took longer than others.

By not taking timely action to pursue revocation, the Department is allowing an individual who does not meet the legal requirements, or who has violated the Act, to continue to access or assist in the dispensing of medical marijuana.

Department lacks policies and procedures for timely revocations

The Department has not developed policies and procedures for ensuring all steps in the revocation process are completed in a timely manner, including establishing internal goals or time frames for these steps. According to best practices issued by the National State Auditors Association, agencies should take appropriate, consistent, and timely enforcement actions.[36] Although some circumstances may reasonably require a longer time period to revoke a card, such as when the Department needs to request additional documentation to determine whether a crime constitutes an excluded felony offense, and some revocation process steps are out of the Department's control, establishing and tracking internal time frames would help guide Department staff and ensure key steps in the revocation process are completed in a timely and consistent manner.

Recommendations

The Department should:

1. Develop and implement policies and procedures for revoking medical marijuana registry identification cards, including developing internal steps and associated time frames for revocation process steps that are within its control.

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[34] The Department did not request additional documentation for the remaining 4 registry identification cards.

[35] This time was calculated from the end of the cardholder's time to appeal the decision until the final revocation letter was sent by the Department. The Department took between 12 and 17 days to send the letter for the 4 remaining cards.

[36] National State Auditors Association. (2004). *Carrying out a state regulatory program: A National State Auditors Association best practices document*. Lexington, KY.

2. Track and oversee performance for the time frames to ensure revocations occur as quickly and consistently as possible.

Department response: As outlined in its **response**, the Department agrees with the finding and will implement the recommendations.

Some medical marijuana facility inspections not completed timely or consistently

Inspections should ensure compliance and protect the public

The Department conducts ongoing compliance inspections of medical marijuana dispensaries and their cultivation sites (medical marijuana facilities). During an inspection, Department staff assess compliance with statutory and rule requirements, such as whether medical marijuana facilities have adequately packaged and labeled medical marijuana and whether a facility has adequate video surveillance of its buildings (see textbox for additional examples). Although neither statute nor rule specify an inspection frequency, the Department reported that its unwritten goal is to inspect each medical marijuana facility at least once each year. In scheduling inspections, staff rely on a Department-managed database that stores various pieces of information about medical marijuana facilities, including the dates of previous compliance inspections.[37] Each month, Department staff query the database to identify which facilities received a compliance inspection a year earlier and are therefore due for an inspection.

After conducting the inspection, the Department provides the medical marijuana facility with a written statement of deficiencies, which lists the specific statutory or rule violation(s) found during the inspection. The medical marijuana facility must then develop and provide the Department with a plan of correction within 20 working days that describes the corrective actions taken to address the violations and prevent their recurrence. Once the Department receives a plan of correction, it is reviewed by Department staff to ensure the facility adequately addressed each violation.

Examples of items assessed at inspections

- Whether medical marijuana in the process of production, preparation, manufacture, packing, storage, sale, distribution, or transportation is protected from flies, dust, dirt, and all other contamination.
- Whether the medical marijuana facility documents each day's beginning inventory, acquisitions, harvests, sales, disbursements, disposal of unusable marijuana, and ending inventory.
- Whether the medical marijuana facility has video cameras that provide coverage of all entrances to and exits from the building and limited access areas.
- Whether product labels include a list of all chemical additives used in the cultivation and production of medical marijuana.

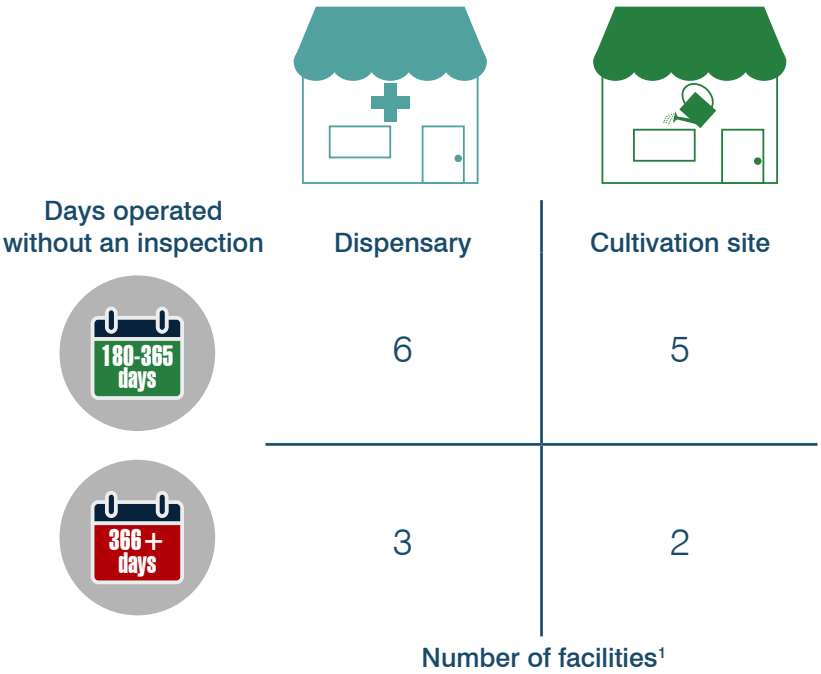
Source: Auditor General staff review of AAC R9-17-316, R9-17-318, and R9-17-320; and the Department's inspection checklist for medical marijuana facilities.

[37] According to A.R.S. §36-2806(H), the Department shall give reasonable notice of an inspection. Further, AAC R9-17-309(B) states that onsite inspections must occur at a date and time that is agreed upon by both the dispensary and the Department. According to the Department, its staff request 3 to 5 potential inspection dates from the medical marijuana facility for an upcoming inspection, and the Department will conduct the inspection on 1 of these dates without providing additional advance notice.

Some inspections not completed timely and compliance inconsistently assessed

Some medical marijuana facilities not inspected frequently—We reviewed a random sample of 10 dispensaries that were in operation as of May 2018, and 7 associated cultivation sites.[38] Specifically, we assessed how frequently these facilities were inspected after they were authorized to operate, which spanned from 2014 to 2018. Although most facilities were inspected at least once a year, we identified 5 facilities that were not inspected in more than a year at one point throughout their certification. Specifically, these 5 facilities operated without an inspection for 380, 400, 454, 463, and 565 days, respectively.

Number of reviewed facilities and days operated without an inspection



[1] One dispensary in our file review began operating about 3 months previously and therefore had not yet received its first compliance inspection.

Long delays between inspections may put the public at risk because the Department cannot effectively ensure these facilities' ongoing compliance with applicable statutory and rule requirements. For example, when conducting an inspection at a cultivation site that did not receive an inspection for more than a year, the Department identified unsanitary conditions that could affect public health. Specifically, the Department found that some equipment used for cultivating medical marijuana was being stored in the bathroom, which could result in bacteria and germs from the equipment transferring to medical marijuana at the cultivation site.

Department inconsistently assessed compliance during inspections—Based on our interviews with Department staff and observation of 5 inspections conducted between January and August 2018, we also found that the Department inconsistently assessed medical marijuana facilities' compliance with rule requirements during inspections.[39] For example:

- According to rule, a dispensary agent should have his/her registry identification card in his/her immediate possession when working or volunteering at a medical marijuana facility.[40] During 2 inspections at separate

[38] Our sample of 10 dispensaries was from 114 total operating dispensaries as of May 2018. One of the 7 cultivation sites closed in December 2016.

[39] We observed 3 compliance inspections, 1 ATO inspection, and 1 complaint inspection.

[40] AAC R9-17-310(A)(6).

facilities, we observed that dispensary agents did not have their cards in their immediate possession, although the agents retrieved their cards either from their car or another area of the dispensary during the inspection. However, Department inspectors noted a violation at 1 facility but not the other. Further, for 1 of the 5 inspections we observed, inspectors did not check the registry identification cards of dispensary agents.

- According to rule, an edible food product label must include the total weight of the product.[41] During 2 inspections we observed, dispensaries had edible food product labels that listed the total weight using different terminology. Inspectors told 1 dispensary to modify its label to say "total weight" rather than "total package," but did not cite it as a violation. However, the other dispensary listed the total weight as "gross weight," and was cited for a labeling violation.

- According to rule, a dispensary must document various items in its inventory control system based on how the dispensary acquired its medical marijuana. For example, if the dispensary acquires medical marijuana from another dispensary, it must document a description of the medical marijuana, including the amount, strain, and batch number, and the name and registry identification number of the dispensary providing the medical marijuana.[42] Some Department inspectors reported that they assess compliance with inventory control requirements by randomly selecting a product at the dispensary and comparing the total amount of product in the dispensary to the amount listed in the dispensary's inventory paperwork. In contrast, another inspector reported that inspectors will look at the paperwork only to ensure everything is documented as required by rule. This inconsistency in reviewing inventory control practices reported by inspectors mirrors our observations. Specifically, we observed inspectors compare the product in the dispensary with the amount listed in the dispensary's inventory paperwork at only 1 of the 3 compliance inspections we observed. However, randomly selecting product to check against the inventory paperwork appears to allow the Department to better monitor compliance with inventory control requirements compared to simply reviewing the inventory paperwork.

An inconsistent inspection process affects the Department's ability to routinely and accurately monitor medical marijuana facility compliance with statutory and rule requirements. Further, inconsistencies among different inspectors may cause confusion among medical marijuana facilities as to what is required to maintain compliance, or it could lead to the perception among medical marijuana facilities that they are being held to different standards.

Department has not developed and implemented adequate policies, procedures, and training for conducting inspections

Various factors contribute to the inspection timeliness and inconsistency concerns noted previously. Specifically:

- **Inspection goal not formally established—**The Department's unwritten goal for conducting compliance inspections of each medical marijuana facility at least once each year has not been formally established. According to best practices for implementing a regulatory program, an agency should establish a schedule to inspect the regulated entities periodically and it should be frequent enough to provide reasonable safeguards for the public.[43] This lack of a written policy may cause confusion among staff regarding expectations related to inspection frequency. In fact, several staff reported that they believed that the goal for inspecting medical marijuana facilities was once every 6 months, not once a year.

- **Staff incorrectly record inspection dates in database—**As previously discussed, Department inspectors generate a list of inspections that occurred 1 year earlier from its inspections database to determine which medical marijuana facilities are due for an inspection. However, this approach may be adversely affected by staff incorrectly entering, or failing to enter, inspection dates into the database. Specifically, if the date of the prior inspection is not entered accurately, the medical marijuana facility may not appropriately appear on

[41] AAC R9-17-317(C).

[42] AAC R9-17-316(C)(3).

[43] National State Auditors Association. (2004). *Carrying out a state regulatory program: A National State Auditors Association best practices document*. Lexington, KY.

the list of facilities that are due for an inspection. Based on our review of the database, several inspection dates were incorrectly recorded or not recorded at all.[44] For example, a cultivation site received a compliance inspection in January 2017, but the date of the compliance inspection was incorrectly entered under the dispensary, not the cultivation site. This incorrect information likely contributed to the cultivation site operating for 565 days without an inspection.

- **Inadequate policies and procedures and training—**The Department has not developed policies and procedures that provide adequate guidance to Department inspectors on how to assess compliance during inspections. The Department's policies and procedures contain high-level instructions, such as "send notice of inspection to dispensary contact" and "conduct inspection," but do not provide needed detail on how to perform these tasks in accordance with statutory and rule requirements and Department standards. The Department also uses checklists to conduct inspections. However, the Department's inspection checklist only lists the rule citation and does not have additional guidance on how to assess compliance with the rules during the inspection.

  Additionally, the Department does not have a formal training program for new inspectors. Although Department staff who perform inspections participate in informal training activities, such as meeting with the Program's team leader and observing other staff conduct inspections, Department inspectors reported that having additional guidance, such as formal training and updated policies and procedures, would be helpful.

To help ensure inspections are conducted appropriately and uniformly, the Department developed a process in 2017 to conduct "consistency meetings" among inspectors and Program management. The goal of these meetings is to discuss the interpretation of statute and rule and agree upon the application. Decisions made during consistency meetings are documented and made available to inspectors for reference purposes. We observed a consistency meeting in July 2018 where inspectors and Program management discussed various statutory and rule requirements, such as how to apply the statutory requirement for a dispensary to have a single, secure entrance.[45] Although consistency meetings may be a helpful tool for the Department to make decisions on how to interpret and apply statutory and rule requirements during medical marijuana inspections, additional policies, procedures, guidance, and training would help the Department ensure it is conducting inspections of medical marijuana facilities consistently, effectively, and timely.

Recommendations

The Department should:

3. Develop and implement policies and procedures for its inspection processes to ensure Department staff apply, assess, and enforce statutory and rule requirements consistently during inspections. The policies and procedures should address: 1) how often inspections should be conducted; 2) how the Department will schedule and track inspections; 3) how to conduct the inspections, including how violations will be assessed; and 4) how to accurately maintain a record of its inspection process and results.

4. Develop and implement a structured training program that comprehensively addresses the Program's inspection policies and procedures.

5. Continue holding and documenting consistency meetings between inspectors and Program management and, as appropriate, consult with its legal counsel regarding decisions reached at consistency meetings.

Department response: As outlined in its **response**, the Department agrees with the finding and will implement the recommendations.

[44] As a result of inspection dates not being accurately recorded, we were unable to use the database to assess inspection frequency for all medical marijuana facilities. We reviewed each facility's individual file, which included inspection checklists, to determine the frequency of inspections for the 10 dispensaries and 7 associated cultivation sites.

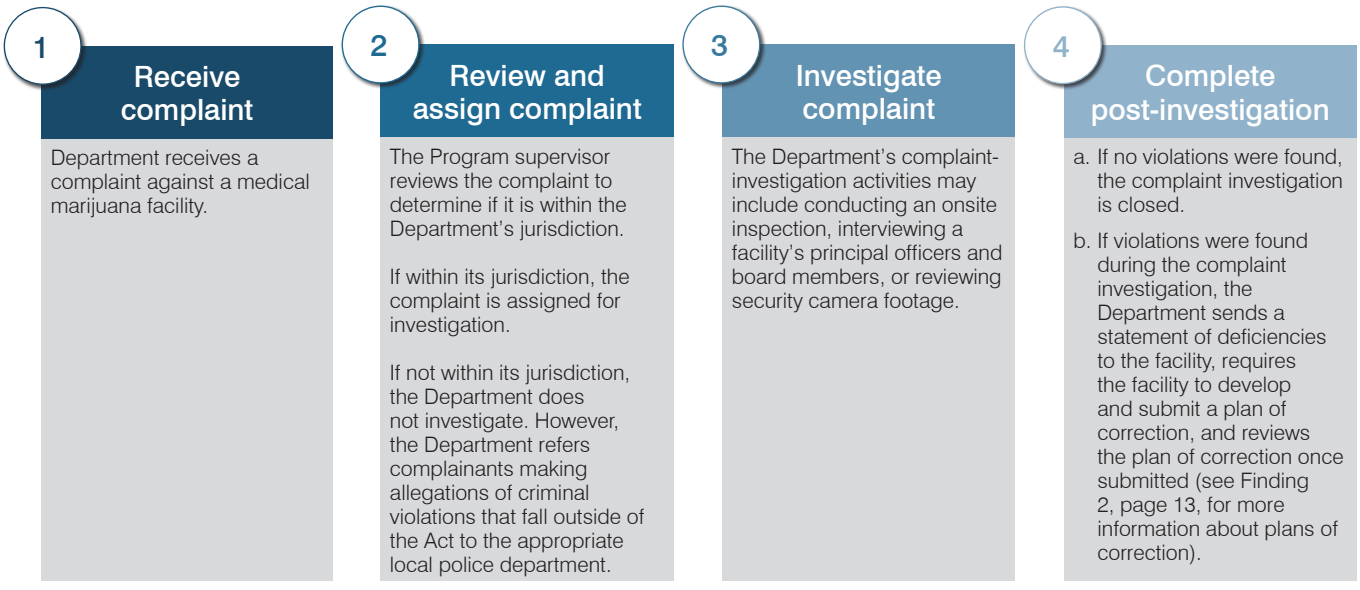
[45] A.R.S. §36-2806(C).

Department has inadequately investigated and monitored some complaints

Department investigates complaints against medical marijuana facilities to help ensure compliance and safety

As part of its statutory authority and responsibility to oversee medical marijuana in the State, the Department investigates complaints concerning medical marijuana facilities. Investigating and resolving complaints helps ensure medical marijuana facilities comply with statute and rule and may also identify threats to public health and safety, such as improper labeling of medical marijuana products or the sale of contaminated marijuana. Complaints against medical marijuana facilities can be submitted using the Department's online complaint system, which records each complaint received in a complaint log. After receipt, the Program's supervisor reported that he manually updates the complaint log throughout the complaint-handling process (see Figure 5 for information on the Department's complaint-handling process). The Department reported that it does not investigate or take additional action for allegations that do not constitute a violation of the Act or its associated rules, such as allegations of poor customer service at a dispensary. However, for those complaints that are determined to be outside its jurisdiction because they do not fall under the Act or its associated rules but may constitute a criminal violation, such as allegations of individuals illegally distributing or selling marijuana, the Department reported that it will refer the complainant to the appropriate local police department.

Figure 5
Department's complaint-handling process for medical marijuana facilities



Source: Auditor General staff review of AAC R9-17-309, Department documents, and interviews with Department staff.

The Department received 291 online complaints against medical marijuana facilities between August 2015 and May 2018. Additionally, according to the Department, between January 2017 and October 2018, it received 6 complaints via email.[46]

Department inadequately investigated some complaints

We reviewed a random sample of 30 online complaints submitted to the Department between August 2015 and May 2018. Specifically, we randomly selected 5 complaints that were substantiated, meaning the Department found evidence to support the complaint's allegations; 5 complaints that were unsubstantiated; and 20 complaints that the Department determined were not within its jurisdiction. We also reviewed the 6 complaints that were received via email. Based on our review of these complaints, we determined that the Department did not adequately investigate some complaints, categorize complaints, or document complaint investigations. Specifically:

- **Some complaints not investigated—**The Department inappropriately determined that 2 complaints were not in its jurisdiction, which resulted in these complaints not being investigated. However, these complaints contained allegations of statute or rule violations related to the Act and were therefore within the Department's authority to investigate. One of these complaints alleged a dispensary was permanently closed. However, rule states that a dispensary must operate and be available to dispense medical marijuana to qualifying patients and designated caregivers at least 30 hours weekly.[47] The second complaint alleged a dispensary had inaccurate product labels, but rule addresses labeling requirements for medical marijuana products.[48] By not appropriately assessing its authority or jurisdiction to investigate complaints, the Department cannot effectively protect public health and safety or address potential violations of statute and/or rule, thereby allowing potential violations of the Act to continue.

- **Some complaints inaccurately categorized after investigation—**The Department investigated 2 complaints that separately alleged a dispensary employed an individual under the age of 21 and that a dispensary agent worked with an expired registry identification card. After completing the investigations for these 2 complaints, the Department determined that no violation of statute or rule occurred.[49] However, instead of determining that these 2 complaints were unsubstantiated, the Department incorrectly determined that these complaints were not in the Department's jurisdiction and recorded them as such in the complaint log.

  Additionally, for an email complaint alleging that a dispensary was selling product that was inaccurately measured, the Department conducted an investigation and found no evidence that supported the allegation. Although some safety violations were found related to product labeling as a result of the investigation, they were not related to the original allegation that prompted the investigation. However, the Department incorrectly determined the allegation of inaccurate product measurements was substantiated. By not appropriately assessing and categorizing complaint outcomes, the Department cannot accurately track trends in violations, such as facilities with repeated substantiated complaints, and take appropriate action.

- **Complaint investigations not adequately documented—**The Department's investigations for 4 of the 10 substantiated and unsubstantiated complaints were not adequately documented, and as a result, we were unable to assess the adequacy of the Department's investigation of these 4 complaints. Once a complaint investigation is complete, Department staff prepare a written statement of deficiencies that outlines any violations that were identified. The statement of deficiencies also includes a description of some of the investigative activities Department staff performed, such as interviewing dispensary agents and performing onsite facility observations. Although the statement of deficiencies outlines violations that were identified during the investigation, it does not describe all of the investigative activities performed. Therefore,

[46] According to the Department, complaints received via email are handled using the same process as online complaints.

[47] AAC R9-17-310(A)(1).

[48] AAC R9-17-317.

[49] The Department did not document the investigative activities for these 2 complaints.

investigative activities for complaint allegations that were unsubstantiated are not documented. For example, the Department investigated a complaint that included 2 separate allegations: 1) an individual under the age of 21 was working at a dispensary, and 2) growing marijuana plants in unauthorized locations of the dispensary. Although the statement of deficiencies included a description of the investigative activities that substantiated the allegation that someone working at the dispensary was under the age of 21, it did not include a description of what actions, if any, were taken to investigate the allegation of plants growing in unauthorized locations.

By not adequately documenting complaint investigations, the Department may not be able to adequately support any enforcement actions that result from complaint investigations. Further, by not documenting all investigative activities, the Department cannot ensure that each allegation was properly investigated.

Department cannot adequately track or monitor complaints because of data entry errors in complaint log

We found that Department staff did not accurately record information in the Department's complaint log. For example, Department staff incorrectly recorded that 1 complaint was resolved on a date prior to the date of the complaint inspection. Another complaint alleging poor customer service at a dispensary was correctly determined to be outside of the Department's jurisdiction but was incorrectly recorded in the complaint log as unsubstantiated. By not maintaining accurate information in the complaint log, the Department cannot effectively use it to monitor or track information related to complaints, such as the timeliness of the complaint-handling process or complaint trends.

Further, the complaint log does not include all complaints the Department receives. Specifically, between January 2017 to October 23, 2018, the Department received at least 6 complaints via email that were not recorded in the complaint log. Although these 6 complaints followed the same process as complaints submitted online, by not recording and tracking these complaints in the complaint log, there is a risk that complaints submitted via email would not be adequately monitored, investigated, and documented.

Complaint-handling policies and procedures are outdated and Department lacks formal training program

Although the Department has developed some complaint-handling policies or procedures for its Public Health Licensing Services Division, which includes the Medical Marijuana Program, these policies do not incorporate practices specific to the Medical Marijuana Program, and a Department official reported that these policies and procedures are outdated. In addition, Department staff reported they were unaware of any complaint-handling policies and procedures. Further, although Department staff receive training and guidance through informal meetings with the Program's supervisor or by shadowing other staff members, the Department does not have a formal complaint-handling and investigation training program to help ensure that complaints are appropriately and consistently assessed, categorized, investigated, and resolved.

According to complaint-handling best practices, agencies should:

- Establish a systematic method for handling complaints and have written complaint-handling guidelines and procedures to help ensure the public, as well as staff, know how complaints will be handled when they are received in order to adequately protect the public.[50]

[50] National State Auditors Association. (2004). *Carrying out a state regulatory program: A National State Auditors Association best practices document*. Lexington, KY; Commonwealth Ombudsman. (2009). *Better practice guide to complaint handling*. Canberra, Australia; New South Wales Ombudsman. (2015). *Complaint management framework*. Sydney, Australia; Queensland Ombudsman. (2006). *Effective complaints management: Guide to developing effective complaints management policies and procedures*. Brisbane, Australia.

- Provide formal training to new inspectors and ongoing training to all staff members to ensure staff have adequate skills to effectively handle complaints.[51]
- Track and oversee complaints in order to ensure they are being addressed timely, appropriately, and effectively so complaints do not go unaddressed.[52]

Recommendations

The Department should:

6. Update and implement policies and procedures for its complaint-handling process, including:
    - Determining and documenting whether complaints are in its jurisdiction.
    - Determining when a secondary review of complaints is necessary to ensure complaints are appropriately assigned for investigation, such as mandating a secondary review for all complaints determined to be outside the Department's jurisdiction.
    - Documenting all complaint investigation activities and any decisions reached from investigations.
    - Establishing time frames for completing key steps of the complaint-handling process.
    - Ensuring each complaint received by the Department is accurately recorded, tracked, and monitored in a complaint log or in another centralized location.
    - Reviewing complaint outcomes and trends, and taking any necessary actions based on the trends identified.
7. Develop and implement training for all staff involved in the complaint-handling process once it has developed the policies and procedures outlined in Recommendation 6, including training for new staff and periodic refresher training for all staff.

    Department response: As outlined in its **response**, the Department agrees with the finding and will implement the recommendations.

[51] NSAA, 2004; Commonwealth Ombudsman, 2009; New South Wales Ombudsman, 2015; Queensland Ombudsman, 2006.

[52] NSAA, 2004; Commonwealth Ombudsman, 2009; New South Wales Ombudsman, 2015; Queensland Ombudsman, 2006.

Department has not consistently addressed medical marijuana facility noncompliance

Department uses various approaches to address facility noncompliance

The Department uses various approaches to address facility noncompliance. Specifically, as noted in Finding 2 (see page 13), a facility is required to develop and submit a plan of correction that describes the corrective actions taken to address any violations found during inspections. The Department reported that for more serious instances of noncompliance, such as repeat violations of health or safety, it will hold "provider meetings" with medical marijuana facilities. During a provider meeting, the Department discusses its concerns and enters into signed agreements with the medical marijuana facility to address violations and ensure similar violations do not occur in the future. Provider meetings can result in various outcomes to address noncompliance (see textbox). For example, the Department may reach a voluntary agreement with a medical marijuana facility to conduct a specified number of unannounced inspections to further monitor the facility and ensure it has returned to compliance.[53]

The Department also has the statutory authority to revoke a dispensary's registration certificate (DRC).[54] The Department can revoke the facility's DRC if the dispensary dispenses, delivers, or transfers marijuana to or acquires marijuana from any person other than another registered dispensary, qualifying patient, or designated caregiver.[55] As of February 2019, the Department reported it had not revoked any DRCs.

Examples of provider meeting outcomes

- May 2018: In response to various violations identified during an inspection, a medical marijuana facility agreed to allow the Department to conduct 4 unannounced inspections during the following year.
- June 2018: A dispensary signed and entered into a voluntary agreement to pay the Department an $11,500 fee for 9 separate rule violations it identified.

Source: Auditor General staff review of the Department's provider meeting agreements.

[53] As noted in Finding 2 (see page 13), the Department is required by A.R.S. §36-2806(H) to give reasonable notice of an inspection. Further, AAC R9-17-309(B) states that onsite inspections must occur at a date and time that is agreed upon by both the dispensary and the Department. Therefore, to conduct unannounced inspections, the Department needs to receive approval from the medical marijuana facility.

[54] Laws 2019, Ch. 318, modified the Department's enforcement authority to allow it to deny, suspend, or revoke a DRC for substantial noncompliance or if the nature or number of violations identified during an inspection or investigation constitutes a threat or direct risk to a qualifying patient's health or safety. Further, it authorizes the Department to assess civil penalties of up to $1,000 per day per violation of statute or rule, up to $5,000 for a 30-day period, and requires the Department to consider certain criteria, such as repeated violations, the type and severity of violations, and the potential for harm, when determining the penalty amount. These changes become effective on August 27, 2019.

[55] A.R.S. §36-2815(B).

Department actions may not effectively address noncompliance

Based on our review of 5 substantiated complaints, we identified some inconsistencies in how the Department addressed similar substantiated violations identified in 4 of these complaints.[56] Specifically:

- Each of the 4 substantiated complaints involved allegations of a dispensary allowing individuals without a registry identification card to work or volunteer as a dispensary agent. Although the Department held a provider meeting with 2 dispensaries, during which it received approval to conduct a specified number of unannounced inspections, the Department requested that the other 2 dispensaries submit a plan of correction to describe how the dispensaries addressed the violations found.

- For 2 substantiated complaints, the Department also found that the dispensaries allowed an individual under the age of 21 to attend trainings or volunteer at the facility.[57] Although the Department requested a provider meeting with 1 dispensary to address the violation, it did not request a provider meeting with the other dispensary. Specifically, the Department had determined that an individual under the age of 21 attended trainings at the dispensary's cultivation site and requested a provider meeting with the dispensary to discuss the violations identified. During the provider meeting, the dispensary agreed to 2 unannounced inspections to help ensure that all individuals working for the dispensary have a registry identification card and are over the age of 21.

  For the second complaint, the Department found that a dispensary allowed a 16-year-old to volunteer at the dispensary and work with qualifying patient records. However, the Department did not request a provider meeting with this dispensary to address this violation and instead requested that the dispensary provide a plan of correction. The dispensary subsequently submitted a plan of correction indicating it had made minor modifications to its policies and procedures, including clarifying who could work at the dispensary. This course of action may not have been adequate because the Department substantiated another complaint at this same dispensary nearly 5 months later that alleged individuals were inappropriately working at the dispensary without registry identification cards. Even after this subsequent violation, the Department did not request a provider meeting and instead required another plan of correction.

Although it may be appropriate to address seemingly similar incidents of noncompliance in different ways when accounting for a facility's history of compliance or other relevant factors, Department staff were not able to explain why different actions were taken in the instances described above, nor were these reasons documented. In addition, failing to escalate corrective actions for repeat offenses may not effectively address or deter noncompliance, which is critical to help ensure public safety and welfare.

Department has not developed guidance or standards for addressing noncompliance by medical marijuana facilities

The Department does not have policies and procedures specific to addressing noncompliance by medical marijuana facilities, including when to seek a provider meeting or when to pursue unannounced inspections, which is likely a contributing factor in the inconsistencies noted previously. According to best practices for implementing a regulatory program, regulatory agencies should develop a systematic, fair, and progressively stringent enforcement process in order to ensure that the public is adequately protected.[58] Additionally, an agency should specify the number or severity of violations that should trigger each level of enforcement action, as well as any applicable time frames for the enforcement action. For example, the Department could determine which statute or rule violations would potentially harm the public health and safety and therefore

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[56] As noted in Finding 3 (see page 17), we randomly selected 30 complaints from the Department's complaint log and reviewed 5 substantiated complaints, 5 unsubstantiated complaints, and 20 complaints the Department determined were not in its jurisdiction, as labeled in the complaint log.

[57] According to A.R.S. §36-2801, a dispensary agent must be at least 21 years old.

[58] National State Auditors Association. (2004). *Carrying out a state regulatory program: A National State Auditors Association best practices document*. Lexington, KY.

require a provider meeting. Although the Department's Public Health Licensing Services Division, which includes the Medical Marijuana Program, has developed an enforcement matrix within its policies and procedures that identifies the enforcement remedy that should be used based on the violation, the severity of the violation, and whether the violation represents a repeat offense, a Department official reported that the policies and procedures are outdated. In addition, multiple Department staff who work in the Program reported they were unaware of these policies and procedures, and the policies, procedures, and enforcement matrix do not address the unique aspects of the Program.

Recommendation

8. The Department should develop and/or update and implement policies and procedures for addressing statutory and rule violations by medical marijuana facilities. These policies and procedures should include guidance for addressing medical marijuana facility noncompliance, such as when to seek a provider meeting and how to conduct provider meetings; the use of unannounced inspections; when to seek monetary penalties; when it should pursue revocation of a dispensary registration certificate; and where to document these decisions. Once these policies are developed and/or updated, all appropriate Program staff should be trained on these policies and procedures.

   Department response: As outlined in its **response**, the Department agrees with the finding and will implement the recommendation.

Although licensed as food establishments, Department does not inspect for food safety requirements at medical marijuana infusion kitchens

Department licenses infusion kitchens as food establishments

One of the Department's statutory responsibilities is to ensure that all retail food and drink in the State is safe for consumption.[59] As such, the Department licenses infusion kitchens at medical marijuana facilities as food establishments.[60,61] Similar to the process for other food establishments in the State, infusion kitchens must undergo a preoperational inspection by a registered sanitarian from the Department's Office of Environmental Health Food Safety and Environmental Services program prior to receiving a license. As part of this inspection, the sanitarian assesses areas such as whether handwashing facilities are available and functional, food condition and source, and contamination prevention. For example, the registered sanitarian will check the temperature of any food or ingredients present, and check food equipment and food storage areas.

Food establishment is an operation that stores, prepares, packages, serves, vends, or otherwise prepares food for human consumption, such as a restaurant.

Infusion kitchens are located at medical marijuana facilities and prepare marijuana-infused edible food products to be sold at dispensaries, such as cookies, brownies, and candy. In October 2018, a dispensary opened the first infusion kitchen in the State to prepare and sell hot, ready-to-eat marijuana-infused edible food products, such as burgers and tacos.

Source: Auditor General staff review of Arizona food code, Department documents, inspection observations, and news articles.

As of December 2018, there were 36 infusion kitchens with food establishment licenses in the State.

Department has failed to conduct ongoing food safety inspections

Although the Department licenses infusion kitchens as food establishments and Arizona's food safety regulations require ongoing food safety inspections for food establishments, the Department does not inspect infusion kitchens for ongoing food safety compliance after conducting the initial preoperational inspection. The Department conducts ongoing compliance inspections of medical marijuana facilities (see Finding 2, pages 13 through 16), but these inspections are not designed to assess compliance with food safety requirements (see textbox, page 26, for examples of food safety requirements). In contrast, the Department, as well as Arizona counties within their respective jurisdictions, conduct ongoing food safety inspections of other licensed food establishments using a risk-based approach that could result in a food establishment receiving 1 to 4 unannounced food safety

[59] A.R.S. §36-136(I)(4).

[60] AAC R9-17-319(A) requires dispensaries to obtain written authorization to prepare, sell, or dispense marijuana-infused edible food products and for dispensaries to ensure marijuana-infused edible food products are prepared, sold, or dispensed according to the State's food safety rules.

[61] Although the Department generally delegates the licensure and regulation of food establishments in the State to the counties, only Coconino County licenses medical marijuana infusion kitchens as food establishments. According to the Department, it has not developed a formal delegation agreement with Coconino County to perform food safety inspections of infusion kitchens.

inspections each year.[62] Because the Department does not conduct ongoing food safety inspections of infusion kitchens, there is a risk that qualifying patients, which include vulnerable populations, are purchasing and consuming food products without adequate oversight to prevent foodborne illnesses.[63] As illustrated in the textbox below, Coconino County officials have identified food safety concerns by conducting ongoing food safety inspections of infusion kitchens.[64]

Examples of food safety requirements for food establishments

- A food employee must wash his/her hands after using the restroom or after handling soiled equipment or utensils.
- Food must be stored at least 6 inches above the floor.
- Except during preparation, cooking, or cooling, food must be maintained at 130°F or above or 41°F or less.
- Food should only contact surfaces of equipment and utensils that are cleaned and sanitized.

Source: Auditor General staff review of AAC R9-8-107 and Arizona food code.

Department should inspect infusion kitchens for ongoing food safety

The Department reported that it does not conduct ongoing food safety inspections of infusion kitchens because medical marijuana facilities typically close infusion kitchens on the dates when the Department has announced that it will conduct a medical marijuana inspection.[65] However, the Department has the responsibility to conduct ongoing food safety inspections of infusion kitchens because it licenses infusion kitchens as food establishments and Arizona's food safety regulations require such inspections for food establishments. Therefore, the Department needs to follow its same practices for inspecting licensed food establishments when it conducts food safety inspections of infusion kitchens. Further, based on our review of food safety requirements and interviews with Department sanitarians, food establishments can be inspected for compliance with various food safety requirements, even if food is not being prepared at the time of inspection, including handwashing, coolers or freezers, food preparation sinks, and the temperature of any food or ingredients in the kitchen.

Case example of food safety concerns identified by food safety inspection of infusion kitchen

Coconino County adopted an ordinance to regulate food safety of edible food products prepared and sold by infusion kitchens in Coconino County. The ordinance authorizes Coconino County to license infusion kitchens as food establishments, thereby allowing the County to conduct food safety inspections both when initially licensing an infusion kitchen as a food establishment and on an ongoing basis. As of January 2019, there are 2 licensed infusion kitchens in Coconino County. As a result of conducting ongoing food safety inspections, Coconino County has identified food safety concerns at infusion kitchens. For example, Coconino County officials found that some food products were not appropriately refrigerated or tested for pathogens and worked with a dispensary to issue a voluntary recall of edible food products in January 2017, including marinara sauce, mustard, and ketchup.

Recommendation

9. The Department should conduct unannounced food safety inspections of infusion kitchens on an ongoing basis, similar to its practices for other licensed food establishments in the State.

   Department response: As outlined in its **response**, the Department does not agree with the finding and will not implement the recommendation.

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[62] According to a Department official, the number of annual food safety inspections per food establishment may vary by county.

[63] As noted in Other Pertinent Information, pages 37 through 38, the Department does not conduct testing of medical marijuana, including edible food products. However, Laws 2019, Ch. 318, requires independent third-party laboratories to begin testing medical marijuana and medical marijuana products for unsafe levels of various items, including microbial contamination, heavy metals, and pesticides beginning in November 2020, before medical marijuana facilities can sell or dispense the products to qualifying patients or designated caregivers.

[64] Although Coconino County conducts food safety inspections of infusion kitchens in that county, the Department still conducts compliance inspections of medical marijuana facilities in the county.

[65] According to A.R.S. §36-2806(H), the Department is required to give a dispensary reasonable notice of an inspection.

Department should establish and implement process for setting Program fees

Department established Program fees

The Department charges medical marijuana registry identification cardholders and medical marijuana facilities (facilities) initial and renewal fees to pay for Program costs, such as the costs associated with reviewing, processing, and issuing registry identification cards (cards).[66,67] The fee amounts are established in rule and vary depending on application type (see Table 2).[68] The Department reported establishing its fees in 2011 based on public comment regarding proposed fee amounts, and by reviewing fees charged by other states' medical marijuana programs (see Table 3, pages 39 through 41, for more information about fee amounts in other states as of 2018).

Table 2
Medical marijuana registry identification cardholders' and facilities' fees

Application Type	Fee amount
Initial or annual renewal card for a qualifying patient[1]	$150
Initial or annual renewal card for a designated caregiver	$200
Initial or annual renewal card for a dispensary agent	$500
Annual dispensary registration certificate renewal	$1,000
Addition of cultivation site/changing dispensary or cultivation site location	$2,500
Initial dispensary registration certificate	$5,000

[1] The fee may be reduced to $75 if the patient receives monies from the Supplemental Nutrition Assistance Program (SNAP) and submits proof of current participation in SNAP.

Source: AAC R9-17-102.

In accordance with statute, the Department deposits fees into the Medical Marijuana Fund (Fund), which had a fund balance of approximately $49.6 million at the end of fiscal year 2018 and an estimated balance of approximately $63.3 million by the end of fiscal year 2019 (see Table 1 in the Introduction, page 7).[69]

[66] As required by A.R.S. §36-2803, the Department has adopted rules establishing application and renewal fees for cardholders and medical marijuana facilities—see AAC R9-17-102.

[67] Laws 2019, Ch. 318, authorizes the Department to establish fees for independent third-party laboratories and independent third-party laboratory agents. These changes become effective on August 27, 2019.

[68] As required by A.R.S. §36-2803, dispensary application and renewal fees may not exceed $5,000 and $1,000, respectively.

[69] A.R.S. §36-2817(A) established the Medical Marijuana Fund, which consists of Program fee revenue.

Department has not reviewed appropriateness of Program fees

According to the Department, it has not undertaken a formal process to review the appropriateness of its Program fee amounts since they were initially set in 2011, nor has it developed a process or identified a time frame in the future for reviewing the fee amounts. Further, it has not conducted a cost analysis of the Program. A cost analysis would include a determination of the full cost of Program services, such as all direct and indirect costs related to processing and issuing medical marijuana cards and dispensary registration certificates.[70] However, without accurate cost information, the Department cannot ensure that its fees are appropriately set, which could result in the fees being set too high or too low.[71] For example, setting fees too low could result in insufficient monies in the Fund to cover Program costs, whereas setting fees too high may result in an undue cost burden placed on Program participants, including cardholders, and the Department may generate and retain more revenue than needed.

Best practices for fee setting recommend formal process

Best practices for government fee setting developed by several government and professional organizations indicate that user fees should be determined based on the costs of providing a service.[72] Specifically, if a service benefits particular individuals or groups, or if some individuals or groups use specific services above and beyond what is normally provided to the general public, government entities may choose to charge fees to these individuals and groups to pay for these services. Fee-setting best practices recommend establishing written policies, procedures, and other guidance, including:

- Calculating the full cost of providing a service in order to provide a basis for setting the fee. Agencies should develop and implement a method for determining and tracking the direct and indirect costs for providing goods and services within a program and create policies and procedures for using this method.
- Adopting formal processes for reviewing, assessing, and updating fees. For example, the formal process should include regularly reviewing revenues and costs; determining if the fee is still necessary and appropriately set; and if the revenue generated by the fee has been spent for approved purposes.
- In assessing costs for agency or program operations, agencies should project and consider future program costs when setting fees and in order to do so, the agency must have adequate cost-of-service information.
- Providing information on fees to the public and allowing for public input. Fee review processes should include considering the effect that any proposed fee changes may have on cardholders, communicating results to stakeholders, and providing opportunities for stakeholder input.

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[70] Direct costs include the salaries, wages, and benefits of employees while they are exclusively working on the delivery of the service, as well as the materials and supplies, and other associated operating costs such as utilities, rent, training, and travel. Indirect costs include shared support functions, such as legal or information technology.

[71] In 2016, 2 cardholders filed a lawsuit against the Department stating that the cardholder fees were too high because of the surplus in the Fund. However, the Maricopa County Superior Court ruled that fee setting is a matter of agency decision based on the language of statute, and stated agencies have the discretion to set fees based on both current and future costs, as per the Arizona Constitution. In October 2018, the Arizona Court of Appeals upheld the Maricopa County Superior Court ruling for the same reasons. The case was not appealed to the Arizona Supreme Court.

[72] We reviewed the following fee-setting best practices: Arizona State Agency Fee Commission. (2012). *Arizona State Agency Fee Commission report*. Phoenix, AZ; Government Finance Officers Association. (2014). *Establishing government charges and fees*. Chicago, IL. Retrieved 1/29/2019 from https://www.gfoa.org/establishing-government-charges-and-fees; Government Finance Officers Association. (2002). *Full cost accounting for government services*. Chicago, IL. Retrieved 1/29/2019 from http://www.gfoa.org/full-cost-accounting-government-services; Michel, R.G. (2004). *Cost analysis and activity-based costing for government*. Chicago, IL: Government Finance Officers Association; Mississippi Joint Legislative Committee on Performance Evaluation and Expenditure Review. (2002). *State agency fees: FY 2001 collections and potential new fee revenues*. Jackson, MS; U.S. Government Accountability Office. (2008). *Federal user fees: A design guide*. Washington, DC; and U.S. Office of Management and Budget. (1993). *OMB Circular No. A 25, revised*. Washington, DC. Retrieved 3/7/2019 from https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.

Recommendation

10. To help ensure medical marijuana fees reflect associated program costs, consistent with fee-setting models outlined in best practices, the Department should:

    a. Develop and implement a method, including associated policies and procedures, for determining the direct and indirect costs for providing the Program.

    b. After developing a cost methodology, determine whether the fees for medical marijuana registry identification cards and medical marijuana facilities should be modified to appropriately align with Program costs.

    c. If fee changes are appropriate, proceed with rulemaking to modify its fees, including seeking an exemption from the rulemaking moratorium as necessary and seeking input from stakeholders.[73]

    d. Develop and implement a process to periodically reevaluate the fees associated with the Program.

    Department response: As outlined in its **response**, the Department agrees with the finding and will implement the recommendations.

[73] In January 2019, Governor Ducey issued an executive order renewing a moratorium on new regulatory rulemaking by State agencies. An agency may seek approval for rulemaking under specified circumstances, including reducing a regulatory burden.

Department misallocated some Medical Marijuana Fund monies

Department must use Fund monies for purposes benefiting Program

The Act established the Medical Marijuana Fund (Fund), and as noted in the Introduction on page 6, the Fund consists of Program fee revenue. Because the Act was passed by voter initiative, the monies from the Fund are protected and can only be used for purposes that further the Act.[74] For example, the Legislature cannot appropriate or divert Fund monies, unless it passes legislation that furthers the purpose of the Act, which must pass each house of the Legislature by a three-fourths vote. In 2018, the Arizona Attorney General provided guidance on the use of Fund monies (see textbox).[75]

Use of Fund monies

The Arizona Attorney General opined that the purposes of the Act include the following, and as such, Fund monies may be used for these purposes:

1. Activities related to distinguishing between medical and nonmedical uses of marijuana.
2. Protecting patients and providers from criminal prosecution.
3. Carrying out, implementing, or administering the Act.

Source: Arizona Attorney General Opinion I18-009.

Department misallocated some Fund monies

The Department has used Fund monies for various purposes, such as paying for salaries and related benefits of its staff who administer the Program; paying for information technology costs related to its online cardholder application system; providing education and outreach, such as a medication safety guide on how to safely store medical marijuana; and issuing medical marijuana program registry identification cards. Although the use of Fund monies must benefit the Program, our review of fiscal year 2018 Fund expenditures identified some costs that were not proportionally allocated relative to the benefit the Program received. Specifically:

- **Payroll expenditures misallocated—**In fiscal year 2018, the Department spent approximately $1.6 million of Fund monies to pay for the salaries of 51 employees who worked on the Program. Some of these employees worked full-time on the Program, while others split their time between the Program and other Department programs or responsibilities. For employees who did not work full-time on the Program, the Department allocated a portion of their salaries to the Fund each pay period, and the remaining portion was paid by other Department monies. According to the Department, employees' supervisors are responsible for determining the specific payroll allocations and for updating the payroll allocation throughout the year, if needed. However, the Department was not able to provide documentation to support how the employees' payroll allocations were established or updated. Based on our review of a fiscal year 2018 listing of employee salaries paid from the Fund, payroll expenditures for some of the 31 employees who did not work full-time on the Program, totaling approximately $603,600, were not appropriately allocated to the Fund. For example, we identified 2 employees with estimated salaries totaling approximately $131,000 that were fully paid by the

[74] Statute continuously appropriates the monies in the Fund and the Department is required to administer the Fund.

[75] In August 2018, the Attorney General issued an Opinion in response to a request from a State legislator concerning the authorized uses of the fees and fines collected by the Department and maintained in the Fund.

Fund in fiscal year 2018; however, these 2 employees worked on other programs or responsibilities that were not related to the Program. Specifically, the Department reported that the 2 employees worked approximately 15 and 5 percent of their time, respectively, on other programs. In addition, the salary for a Department official who helps oversee the Program in addition to other Department responsibilities was allocated to the Fund for only the last 8 weeks in fiscal year 2018; however, this official oversaw the Program the entire fiscal year.

- **Some Fund expenditures benefited other programs but costs were not proportionally allocated—** We reviewed a judgmental sample of 65 of 7,177 fiscal year 2018 Fund expenditure transactions. These sampled expenditures totaled approximately $2.6 million of the Fund's $8.8 million total expenditures in fiscal year 2018, excluding payroll and travel expenditures. Although we did not identify any transactions that were entirely unrelated to the Program's operation, we found that some Fund monies were used for purchases that also benefited nonprogram activities. Specifically, for 30 of the 65 transactions we reviewed, totaling approximately $962,000, the Fund paid the full cost of the transaction, but other Department programs also benefited from the expenditures. In addition, the Department lacked documentation supporting why the Fund incurred the full cost. Some key examples include:

  - **Access fees related to the State's Controlled Substances Prescription Monitoring Program (CSPMP) database—**For 2 transactions totaling $600,000, the Fund was used to pay the entire cost of an access fee that allows physicians and pharmacists in the State to more easily access the CSPMP database.[76] Established in 2007, the CSPMP is a database managed by the Arizona State Board of Pharmacy (Pharmacy Board) that contains the prescription records of individuals in the State who were prescribed a controlled substance, such as opioids or stimulants. Statute and rule require physicians and pharmacists to check the CSPMP before prescribing or dispensing certain substances for medicinal purposes, such as opioids, or prior to certifying a patient for medical marijuana.[77,78] According to a Pharmacy Board official, physicians indicated that having to separately log into the CSPMP was cumbersome. Therefore, the access fee was used to create a software gateway, or link, whereby physicians would be able to readily access a patient's prescription history when retrieving the patient's electronic health record without having to separately log into the CSPMP database. The Department reported that it used Fund monies to pay for the entire CSPMP access fee because it believed it was important to provide easier access for physicians to certify patients for medical marijuana and that it considered any benefits to other programs as ancillary benefits.

    Although the Program benefited from paying the CSPMP access fee, no other entities who use, manage, or otherwise benefit from or are involved with the CSPMP contributed toward these costs. For example, in 2017, Governor Ducey declared a state of emergency related to the opioid overdose epidemic. As part of an effort to address the emergency, a CSPMP task force, consisting of the Department, the Pharmacy Board, other State agencies, and interest groups, was convened to develop strategies and goals to identify improvements to the CSPMP, such as assisting healthcare providers with linking electronic health records to the CSPMP. However, the Department did not provide documentation to demonstrate that it had evaluated how or whether to allocate the access fee cost among other agencies or programs, such as the Pharmacy Board or other Department programs. Further, the Department plans to continue using Fund monies to pay for the access fee in fiscal year 2019, for a total of $750,000.

  - **Computer equipment—**For 10 transactions totaling over $17,000, the Department used Fund monies to purchase 2 desktop computers costing approximately $4,600 each and 2 laptop computers costing approximately $2,600 each, as well as technical support and associated equipment. The Department reported that it purchased these computers to develop a new online cardholder application system. Based on interviews with 2 staff who were assigned 3 of the 4 computers, we found that at least 1 of the computers was used for other Department programs. However, the Department did not allocate any of

[76] Although not in the sample, we also found that the Department used the Fund to pay the entire fiscal year 2017 access fee of $425,000.

[77] A.R.S. §36-2606.

[78] Although not required by the Act or specified in statute, AAC R9-17-202(F) requires physicians to check the CSPMP when certifying the use of medical marijuana.

the computer costs to these other programs and did not provide documentation to support using Fund monies to fully pay for this expenditure. Although using some Fund monies to purchase computers and related equipment that benefit the Program is reasonable and allowable, because at least 1 of the computers has been used for purposes not benefiting the Program, a portion of those costs should have been allocated to other Department programs or services.

Additionally, although the Department partially allocated expenditures to other programs for some of the transactions we reviewed, the Department did not have documentation supporting how the allocation amounts were determined. Specifically, for 5 of 65 transactions reviewed, the Department paid a total of approximately $50,000 for employee-related costs such as dues, training, and tuition reimbursements, and consulting services, and it allocated some of these expenditures to the Fund and other programs. According to the Department, it based the allocations on the percentage of time the related employee or contractor worked on the Program or other programs; however, the Department did not provide documentation to support these allocations.

The Fund or other Department programs may be impacted by misallocations

If the Department misallocates costs to the Fund, funding for other Department programs may be impacted. For example, if the Department did not appropriately allocate costs to the Fund based on the benefit received by the Program, other programs may have paid for more than the benefits they received. Conversely, if the Fund paid more than the benefit the Program received, the Department risks violating the Act. Further, it is important to ensure that the Fund is paying only for allowed activities so that Program fees can be set appropriately (see Finding 6, pages 27 through 29, for additional information on the fee-setting process).

Inadequate guidance to ensure appropriate spending of Fund monies

In administering government programs, standards recommend that agencies establish and implement written policies and procedures that provide guidance for spending restricted monies, including policies that address allocation of costs, and development of a monitoring mechanism to evaluate expenditures (see textbox). However, the Department has not developed written policies and procedures regarding the use of Fund monies that could assist the Department in determining whether an expenditure is allowable and whether the expenditures should be allocated to the Fund and/or other Department programs, including appropriate policies and procedures for approving and reviewing expenditures.

Select State and federal standards for spending monies

State and federal guidelines establish the following requirements for expending monies:

1. Establish written policies and procedures to achieve objectives and respond to risks.
2. Evaluate and monitor compliance with statutes and regulations.
3. Ensure costs are necessary and reasonable for the performance of the program and adequately documented.
4. Use direct cost allocation when possible, and when not, allocate costs proportionally to the benefit received. If neither of those alternatives are possible, allocate costs when the cost benefits 2 or more projects or activities on a reasonable documented basis.
5. Charge salaries and wages based on records that accurately reflect the work performed.

Source: *State of Arizona Accounting Manual*; U.S. Government Accountability Office. (2014). *Standards for internal control in the federal government*. Washington, DC; 2 CFR 200.403, 2 CFR 200.404, and 2 CFR 200.430.

As of April 2019, the Department reported that it had established a Department-wide process for required approvals of expenditures based on the amount of each transaction. This process was established to help

ensure expenditures are approved by management who have the operational, procedural, and financial expertise to determine the appropriateness of the transaction, including ensuring that the monies are allocated properly. In addition, according to the Department, all transactions will require finance manager approval to ensure the monies are properly accounted for, including being charged to the correct funding source.

Recommendations

The Department should:

11. Establish and implement written policies and procedures regarding the use of Fund monies that include the following: 1) the Program expenditures that are allowable under the Act; 2) how to allocate expenditures when more than 1 Department program benefits from the expenditure; 3) the processes and documentation necessary to charge payroll costs to the Fund to ensure it is only charged for the work employees perform on the Program; 4) the type of supporting documentation that should be prepared and retained for all Fund expenditures; and 5) a description of monitoring activities, including any supervisory responsibilities, that will help ensure that Fund monies are being spent in accordance with the Act.

    Department response: As outlined in its **response**, the Department disagrees with the finding, but will implement the recommendation.

12. Continue using its required approval plan to help ensure that Fund monies are appropriately approved and accounted for.

    Department response: As outlined in its **response**, the Department agrees with the finding and will implement the recommendations.

Arizona's regulation of medical marijuana compared to other states

As of March 2019, we identified 33 states and the District of Columbia that have legalized and regulate medical marijuana. We contacted officials in 3 western states—Colorado, Nevada, and Washington—and reviewed these states' medical marijuana statutes and regulations in the following areas: regulatory structure; requirements for patients to use, possess, and cultivate medical marijuana; oversight of healthcare practitioners who recommend medical marijuana to patients; inventory control processes at medical marijuana businesses; frequency and process for inspecting medical marijuana businesses; enforcement authority; testing requirements for medical marijuana; and regulating medical marijuana infusion kitchens. We found that Colorado's, Nevada's, and Washington's medical marijuana programs vary in regulatory structure and approach when compared to Arizona's.

For more information on other states that have legalized and regulate medical marijuana, see Table 3, pages 39 through 41.

Regulatory structure

In Arizona, the Department is the only agency that has the responsibility to oversee and regulate medical marijuana. In contrast, all 3 of the other states we contacted divide the responsibility for regulating medical marijuana between 2 state agencies—1 to regulate the facilities that produce/sell marijuana and the other to oversee patients who use medical marijuana. Specifically:

- Colorado's Department of Revenue regulates medical marijuana providers, and the Department of Public Health and Environment oversees the patients who use medical marijuana.
- Nevada's Department of Taxation regulates medical marijuana establishments, and the Department of Health and Human Services oversees the patients who use medical marijuana.
- Washington State's Liquor and Cannabis Board regulates medical marijuana facilities, and the Department of Health oversees the patients who use medical marijuana.

Requirements for patients to use, possess, and cultivate medical marijuana

Requirements to use medical marijuana in Arizona are generally similar to other states' requirements, including obtaining appropriate documentation from a physician or other healthcare provider who diagnoses the patient with a qualifying medical condition and recommends the use of medical marijuana, and a fee.

Arizona, Colorado, and Nevada each require patients to register with the applicable state agency that oversees patients and obtain a medical marijuana card that is valid for 1 to 2 years to legally use, possess, and cultivate medical marijuana. However, adult patients in Washington can voluntarily register with the state's medical marijuana authorization database. Washington patients who choose to register and obtain a card receive additional legal protections and increased marijuana possession limits, but patients may use medical marijuana without registering if they have a completed medical marijuana authorization form signed by their medical provider.

Additionally, all 4 states allow patients to cultivate marijuana in their homes under specific circumstances and limit the amount of usable marijuana and plants that a patient may possess. However, Colorado and Washington allow the patient's healthcare provider to recommend a higher amount if medically necessary.

Oversight of healthcare practitioners

Neither statute nor rule requires the Department to provide physician oversight. However, the Department has developed some oversight mechanisms, including working with the Arizona State Board of Pharmacy to check the number of times a certifying physician checked the Controlled Substances Prescription Monitoring Program as part of completing certifications for medical marijuana, as required by rule.[79] Additionally, according to Department staff, they perform a quarterly comparison of certifying physicians and active dispensary medical directors to identify any potential instances of a medical director who is also acting as a certifying physician, which is prohibited by rule (see Introduction, pages 3 through 4).[80]

For all 4 states, complaints against healthcare practitioners are typically investigated by the practitioners' licensing board. However, each of these states' medical marijuana regulatory agencies has varying degrees of authority to enforce healthcare practitioners' violations of medical marijuana statutes and rules. In addition, the level of oversight of healthcare practitioners who recommend medical marijuana as a treatment for a qualifying health condition varies by state. For example:

- The Colorado Department of Public Health and Environment can sanction healthcare practitioners for violations of medical marijuana rule, such as performing medical evaluations at locations where medical marijuana is sold, and may revoke or suspend a practitioner's ability to certify a qualifying debilitating medical condition and recommend medical marijuana.

- In Nevada, similar to Arizona, the healthcare practitioner's written recommendation for medical marijuana is submitted by the patient as part of his/her application rather than directly by the physician. Nevada also reported calling the offices of all new healthcare practitioners who have not previously signed a recommendation, as well as a random sample of healthcare practitioners who have previously signed a recommendation, to confirm that the healthcare practitioner did indeed sign the patient's recommendation for medical marijuana. Nevada reported it has not identified any fraudulent certifications as of January 2019.

  In addition, Nevada's regulations require the Nevada Department of Health and Human Services to track information related to physicians advising patients to use medical marijuana, including the number of patients that each physician advises to use medical marijuana, as well as the number of times and frequency the physician advises each patient. Based on that information, if Nevada's Department determines that the physician is advising patients to use medical marijuana at a rate that appears unreasonably high, it must notify the applicable licensing board.

- Washington statute authorizes the State's health licensing boards to investigate and determine physicians' compliance with medical marijuana statutes.

Inventory control process at dispensaries and cultivation sites

Arizona rule requires each dispensary to develop, document, and implement an inventory control process, and to submit policies and procedures for this process to the Department in order to apply for a dispensary registration certificate (see Finding 2, page 15, for more information on inventory control). In addition, each dispensary must conduct and document an audit of the dispensary's inventory every 30 calendar days and maintain documentation of the audits for 5 years. Program inspectors should check these inventory audits during inspections.

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[79] AAC R9-17-202(F)(5)(i)(iii).

[80] AAC R9-17-313(E).

The other 3 states use web-based central inventory control mechanisms that all medical marijuana businesses must use to track certain information, such as when marijuana is harvested, transported, or destroyed.

Inspection frequency and process

Arizona statute requires the Department to give dispensaries reasonable notice of the inspection, and rule further specifies that the inspection must occur at a date and time agreed to by the dispensary and the Department. In contrast, none of the other 3 states we contacted require advanced notice for inspections.

Although neither Arizona statute nor rule specifies an inspection frequency, the Department reported its goal is to inspect medical marijuana facilities at least once each year (see Finding 2, page 13). Similar to Arizona, statutes and rules in Colorado, Nevada, and Washington do not specify how frequently medical marijuana dispensaries should be inspected. In practice, each of the other states has developed its own inspection frequencies and methods. Officials from each state reported the following:

- Colorado has developed a risk-based approach to inspections. Specifically, it will conduct a monthly desk review of a medical marijuana facility's records using an inventory tracking system to check for anomalies in the records, such as marijuana plants that grew in a shorter amount of time than expected. Based on this desk review, it will conduct an on-site inspection of approximately 30 percent of the facilities that had anomalies in the inventory records.
- Nevada inspects all facilities at least annually.
- Washington inspects marijuana retail stores 3 times each year and performs inspections of other types of medical marijuana facilities, such as marijuana producers and processors, based on risk.

Enforcement

Arizona uses various approaches to address facility noncompliance, such as requiring a facility to develop and submit a plan of correction after an inspection and holding provider meetings with some facilities that have more serious instances of noncompliance (see Finding 4, page 21). Additionally, Arizona statute provides the Department authority to revoke a dispensary's registration certificate if the dispensary or its agents dispense, deliver, or otherwise transfer marijuana to a person who is not authorized to have it.[81] In comparison, the Nevada Department of Taxation can suspend a marijuana establishment's license and request a written plan of correction for any deficiencies discovered, as well as impose a range of civil penalties based on the severity of the infraction. Colorado rule similarly outlines a range of penalties, including fines, license revocation, suspension, or restriction. Washington's rules outline a range of penalties for violations, ranging from monetary fines to cancellation of a license, and an official from the Washington State Liquor and Cannabis Board reported that the Board's investigators are sworn police officers who have both administrative enforcement powers and criminal enforcement authority related to controlled substances.

Testing requirements for medical marijuana

Arizona rule requires dispensaries to provide samples of product to the Department upon request to conduct an analysis of the medical marijuana, but the Department reported that it has not conducted any testing of medical

[81] Laws 2019, Ch. 318, modified the Department's enforcement authority to allow it to deny, suspend, or revoke a DRC for substantial noncompliance or if the nature or number of violations identified during an inspection or investigation constitutes a threat or direct risk to a qualifying patient's health or safety. Further, it authorizes the Department to assess civil penalties on cardholders and facilities of up to $1,000 per day per violation of statute or rule, up to $5,000 for a 30-day period, and requires the Department to consider certain criteria, such as repeated violations, the type and severity of violations, and the potential for harm, when determining the penalty amount. These changes become effective on August 27, 2019.

marijuana, including edible food products, for 2 reasons.[82] First, the Department reported that federal funding for its laboratory could be at risk if the laboratory were used to test marijuana, and second, statute does not allow non-cardholders, such as laboratory staff, to possess marijuana. However, Laws 2019, Ch. 318, requires independent third-party laboratories to begin testing medical marijuana and medical marijuana products for unsafe levels of various items, including microbial contamination, heavy metals, and pesticides in November 2020. Also, effective August 27, 2019, Laws 2019, Ch. 318, requires the Department to regulate and certify testing laboratories.

In contrast, the 3 other states have established mandatory testing requirements for potency, pesticides, and other contaminants. Specifically:

- Both Nevada and Washington require a sample of each batch, lot, or production run of medical marijuana and medical marijuana product to be tested by a certified laboratory, such as testing for potency and for pesticides.
- Colorado rule requires medical marijuana businesses to submit samples of products to a medical marijuana testing facility to test for potency or contaminants. Colorado uses a risk-based approach through process validation, which means if a marijuana business passes a certain number of tests for potency or contamination, their cultivation or production process is considered validated and they no longer must have every batch of product tested.

Edibles and kitchens

Arizona and the 3 other states have varying approaches in regulating medical marijuana infusion kitchens. Specifically:

- In Arizona, the Department licenses medical marijuana infusion kitchens as food establishments, and rule requires kitchens to operate in accordance with food safety requirements (see Finding 5, pages 25 through 26). Department sanitarians perform an initial preoperational kitchen inspection during the facility's initial food establishment licensing process, but infusion kitchens are not subsequently inspected for food safety requirements.[83]
- Similar to Arizona, rules for Colorado and Washington require marijuana kitchens to comply with all kitchen-related health and safety standards for retail food establishments. According to an official in Washington, the Washington State Department of Agriculture inspects kitchens that process marijuana-infused edible food products prior to issuing a kitchen "endorsement." Inspections are then conducted annually. However, according to an official in Colorado, medical marijuana kitchens in Colorado are not licensed as food establishments and health and safety inspections are usually conducted by local jurisdictions.
- In Nevada, at least 1 marijuana kitchen employee is required to obtain food-handling certification. Kitchens are required to obtain written authorization from the Department of Taxation to prepare edible marijuana products. Nevada rule exempts marijuana kitchens from statutory requirements for food establishments but establishes various food safety rules that marijuana kitchens must follow.

[82] AAC R9-17-317(D).

[83] Coconino County adopted an ordinance to regulate infusion kitchens in Coconino County. As a result, infusion kitchens in Coconino County are licensed and inspected by the Coconino County Public Health Services District.

Table 3
Comparison of states that have legalized and regulate medical marijuana
As of June 2018[1]

State	Year approved or passed	Passed by bill or ballot initiative?	Recreational marijuana allowed? (Y/N)	Home cultivation allowed? (Y/N)	Fees for patient cardholders (initial and renewal)	Length of time a patient card is valid	Legal amount for patients to possess and if authorized, cultivate[2]
Alaska	1998	Ballot initiative (Measure 8)	Y	Y	Initial: $25 Renewal: $20	1 year	1 oz. usable marijuana; 6 plants (3 mature/ flowering)
Arizona	2010	Ballot initiative (Proposition 203)	N	Y	Initial: $150 Renewal: $150	1 year	2.5 oz. marijuana per 14-day period; 12 plants
Arkansas	2016	Ballot initiative (Issue 6/ Medical Marijuana Amendment)	N	N	Initial: $50 Renewal: $50	1 year	2.5 oz. usable marijuana per 14-day period
California	1996	Ballot initiative (Proposition 215)	Y	Y	Initial and renewal: Fees vary by county, not to exceed $100	1 year	8 oz. dried marijuana; 6 mature or 12 immature plants
Colorado	2000	Ballot initiative (Ballot Amendment 20)	Y	Y	Initial: $25 Renewal: $25	1 year	2 oz. usable marijuana; 6 plants (3 mature/ flowering)
Connecticut	2012	Bill (HB 5389)	N	N	Initial: $100 Renewal: $100	1 year	2.5 oz. per month
Delaware	2011	Bill (SB 17)	N	N	Initial: $125 Renewal: $125	1 year	6 oz. (dispensaries may not sell more than 3 oz. to a patient per 14-day period)
Florida	2016	Ballot initiative (Amendment 2/ Medical Marijuana Legalization Initiative)	N	N	Initial: $75 Renewal: $75	1 year	Possession limits have not yet been established by rule.
Hawaii	2000	Bill (SB 862)	N	Y	Initial: $35 fee plus $3.50 portal administration charge Renewal:$35 fee plus $3.50 portal administration charge	1 year	4 oz. usable cannabis every 15 days; 10 plants
Illinois	2013	Bill (HB 1)	N	N	Initial and renewal: $100 one-year registry; $200 two-year registry; $250 three-year registry	1, 2, or 3 years	2.5 oz. usable cannabis per 14-day period

Table 3 continued

State	Year approved or passed	Passed by bill or ballot initiative?	Recreational marijuana allowed? (Y/N)	Home cultivation allowed? (Y/N)	Fees for patient cardholders (initial and renewal)	Length of time a patient card is valid	Legal amount for patients to possess and if authorized, cultivate[2]
Louisiana	2017	Bill (SB 35)	N	N	n/a	n/a	1-month supply, as determined by physician
Maine	1999	Ballot initiative (Question 2)	Y	Y	No fee	1 year	2.5 oz. usable marijuana; 6 plants
Maryland	2014	Bill (HB 881/SB 923)	N	N	Initial: $50 Renewal: $50	2 years	120 grams (approx. 4 oz.) usable cannabis
Massachusetts	2012	Ballot initiative (Question 3)	Y	Y	Initial: $50 Renewal: $50	1 year	10 oz. (60-day supply)
Michigan	2008	Ballot initiative (Proposal 1)	N	Y	Initial: $60 Renewal: $60	2 years	2.5 oz. usable marijuana; 12 plants
Minnesota	2014	Bill (SF 2470)	N	N	Initial: $200 Renewal: $200	1 year	A 30-day supply, amount to be determined by the manufacturer's pharmacist
Montana	2004	Ballot initiative (Initiative 148)	N	Y	Initial: $5 Renewal: $5	1 year	1 oz. usable marijuana; 4 mature/ flowering plants and 12 seedlings
Nevada	2000	Ballot initiative (Ballot Question 9)	Y	Y	Initial: $100 Renewal: $75	1 year	2.5 oz. usable marijuana per 14-day period; 12 plants
New Hampshire	2013	Bill (HB 573)	N	N	Initial: $50 Renewal: $50	1 year	2 oz. usable marijuana per 10-day period
New Jersey	2010	Bill (SB 119)	N	N	Initial: $200 Renewal: $200	2 years	2 oz. maximum per 30-day period, as directed by physician
New Mexico	2007	Bill (SB 523)	N	Y	No fee	1 year	230 units (8 oz) per 3-month period; 4 mature plants and 12 seedlings
New York	2014	Bill (Assembly Bill 6357)	N	N	Initial: $50 Renewal: $50	1 year	30-day supply, as determined by physician
North Dakota	2016	Ballot initiative (Measure 5)	N	Y	Initial: $50 Renewal: $50	1 year	3 oz. usable marijuana per 14-day period; 8 plants
Ohio	2016	Bill (HB 523)	N	N	Initial: $50 Renewal: $50	1 year	90-day supply determined by rule
Oklahoma	2018	Ballot initiative (Ballot Question 788)	N	Y	Initial: $100 Renewal: $100	2 years	3 oz. marijuana on person; 8 oz. at residence; 6 mature plants and 6 seedlings

Table 3 continued

State	Year approved or passed	Passed by bill or ballot initiative?	Recreational marijuana allowed? (Y/N)	Home cultivation allowed? (Y/N)	Fees for patient cardholders (initial and renewal)	Length of time a patient card is valid	Legal amount for patients to possess and if authorized, cultivate[2]
Oregon	1998	Ballot initiative (Ballot measure 67/Oregon Medical Marijuana Act)	Y	Y	Initial: $200 Renewal: $200	1 year	24 oz. usable marijuana; 6 mature plants and 18 seedlings
Pennsylvania	2016	Bill (SB 3)	N	N	Initial: $50 Renewal: $50	1 year	30-day supply
Rhode Island	2006	Bill (SB 0710)	N	Y	Initial: $50 Renewal: $50	1 year	2.5 oz. usable marijuana;12 plants and 12 seedlings
Vermont	2004	Bill (SB 76)	Y	Y	Initial: $50 Renewal: $50	1 year	2 oz. usable marijuana; 2 mature plants and 7 immature plants
Washington	1998	Ballot initiative (Initiative 692)	Y	Y	Initial: $1 Renewal: $1	1 year (6 months for minors)	3 oz. usable marijuana; 6 plants—possess up to 8 oz. from plants
Washington, DC	2010	Bill (L18-0210/ Amendment Act B18-622)	Y	N	Initial: $100 Renewal: $100	1 year	2 oz. dried per 30-day period
West Virginia	2017	Bill (SB 386)	N	N	Initial: $50 Renewal: $50	1 year	30-day supply, amount to be determined

[1] As of March 2019, Missouri and Utah had also passed medical marijuana legislation.

[2] Some states only permit cultivation if the patient meets certain conditions. For example, in Arizona, a qualifying patient may cultivate marijuana if living more than 25 miles from a certified medical marijuana dispensary.

Source: Auditor General staff review and summary of state statutes and rules and 3 compendia: National Alliance for Model State Drug Laws. (2017). *Marijuana: Comparison of state laws allowing use for medical purposes*. Manchester, IA. National Conference of State Legislatures. (n.d.). *State medical marijuana laws*. Retrieved 7/10/2018 from http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx. ProCon.org. (n.d.). *30 legal medical marijuana states and DC: Laws, fees and possession limits*. Santa Monica, CA.

Auditor General makes 12 recommendations to the Department

The Department should:

1. Develop and implement policies and procedures for revoking medical marijuana registry identification cards, including developing internal steps and associated time frames for revocation process steps that are within its control (see Finding 1, pages 9 through 12, for more information).

2. Track and oversee performance for the time frames to ensure revocations occur as quickly and consistently as possible (see Finding 1, pages 9 through 12, for more information).

3. Develop and implement policies and procedures for its inspection processes to ensure Department staff apply, assess, and enforce statutory and rule requirements consistently during inspections. The policies and procedures should address: 1) how often inspections should be conducted; 2) how the Department will schedule and track inspections; 3) how to conduct the inspections, including how violations will be assessed; and 4) how to accurately maintain a record of its inspection process and results (see Finding 2, pages 13 through 16, for more information).

4. Develop and implement a structured training program that comprehensively addresses the Program's inspection policies and procedures (see Finding 2, pages 13 through 16, for more information).

5. Continue holding and documenting consistency meetings between inspectors and Program management and, as appropriate, consult with its legal counsel regarding decisions reached at consistency meetings (see Finding 2, pages 13 through 16, for more information).

6. Update and implement policies and procedures for its complaint-handling process, including:

    - Determining and documenting whether complaints are in its jurisdiction.
    - Determining when a secondary review of complaints is necessary to ensure complaints are appropriately assigned for investigation, such as mandating a secondary review for all complaints determined to be outside the Department's jurisdiction.
    - Documenting all complaint investigation activities and any decisions reached from investigations.
    - Establishing time frames for completing key steps of the complaint-handling process.
    - Ensuring each complaint received by the Department is accurately recorded, tracked, and monitored in a complaint log or in another centralized location.
    - Reviewing complaint outcomes and trends, and taking any necessary actions based on the trends identified (see Finding 3, pages 17 through 20, for more information).

7. Develop and implement training for all staff involved in the complaint-handling process once it has developed the policies and procedures outlined in Recommendation 6, including training for new staff and periodic refresher training for all staff (see Finding 3, pages 17 through 20, for more information).

8. Develop and/or update and implement policies and procedures for addressing statutory and rule violations by medical marijuana facilities. These policies and procedures should include guidance for addressing

medical marijuana facility noncompliance, such as when to seek a provider meeting and how to conduct provider meetings; the use of unannounced inspections; when to seek monetary penalties; when it should pursue revocation of a dispensary registration certificate; and where to document these decisions. Once these policies are developed and/or updated, all appropriate Program staff should be trained on these policies and procedures (see Finding 4, pages 21 through 23, for more information).

9. Conduct unannounced food safety inspections of infusion kitchens on an ongoing basis, similar to its practices for other licensed food establishments in the State (see Finding 5, pages 25 through 26, for more information).

10. Ensure medical marijuana fees reflect associated program costs, consistent with fee-setting models outlined in best practices. Specifically, the Department should:

    a. Develop and implement a method, including associated policies and procedures, for determining the direct and indirect costs for providing the Program.

    b. After developing a cost methodology, determine whether the fees for medical marijuana registry identification cards and medical marijuana facilities should be modified to appropriately align with Program costs.

    c. If fee changes are appropriate, proceed with rulemaking to modify its fees, including seeking an exemption from the rulemaking moratorium as necessary and seeking input from stakeholders.

    d. Develop and implement a process to periodically reevaluate the fees associated with the Program (see Finding 6, pages 27 through 29, for more information).

11. Establish and implement written policies and procedures regarding the use of Fund monies that include the following: 1) the Program expenditures that are allowable under the Act; 2) how to allocate expenditures when more than 1 Department program benefits from the expenditure; 3) the processes and documentation necessary to charge payroll costs to the Fund to ensure it is only charged for the work employees perform on the Program; 4) the type of supporting documentation that should be prepared and retained for all Fund expenditures; and 5) a description of monitoring activities, including any supervisory responsibilities, that will help ensure that Fund monies are being spent in accordance with the Act (see Finding 7, pages 31 through 34, for more information).

12. Continue using its required approval plan to help ensure that Fund monies are appropriately approved and accounted for (see Finding 7, pages 31 through 34, for more information).

Objectives, scope, and methodology

The Office of the Auditor General conducted this performance audit of the Department pursuant to a September 14, 2016, resolution of the Joint Legislative Audit Committee. The audit was conducted as part of the sunset review process prescribed in Arizona Revised Statutes (A.R.S.) §41-2951 et seq. The audit addresses the Department's regulation of the Medical Marijuana Program.

We used various methods to address the audit's objectives. These methods included interviewing Department management and staff and reviewing applicable State laws and rules, policies and procedures, and the Department's website. We also used the following specific methods to meet the audit's objectives:

- To determine whether the Department provides adequate oversight for the registry identification card process, including issuing registry identification cards to only qualified applicants in a timely manner, we reviewed a random sample of 30 qualifying patient, 10 designated caregiver, and 10 dispensary agent registry identification cardholder applications approved in fiscal year 2018. We selected the random sample from the population of active cardholders as of June 30, 2018, which consisted of 172,227 qualifying patients, 913 designated caregivers, and 5,261 dispensary agents. We also reviewed a random sample of 5 of the 49 qualifying patient applications and 5 of the 33 dispensary agent applications that were denied in fiscal year 2018 to determine whether applications were appropriately denied. Additionally, to determine the appropriateness and timeliness of registry cardholder revocations, we reviewed a random sample of 10 of the 35 registry identification cards that were revoked in fiscal year 2018. Finally, to assess how the Department oversees physicians who certify qualifying patients for medical marijuana, we interviewed officials from the Arizona State Board of Pharmacy, Arizona Medical Board, Arizona Board of Osteopathic Examiners in Medicine and Surgery, and the Arizona Naturopathic Physicians Medical Board.

- To determine whether the Department's inspection and enforcement processes were effective to oversee medical marijuana facilities' compliance with statutory and rule requirements, we reviewed the Department's inspection checklist and observed 5 inspections conducted between January and August 2018.[84] We also reviewed a random sample of 10 of the 114 dispensaries that were in operation as of May 2018, and 7 associated cultivation sites. We reviewed every inspection that occurred since the dispensaries' or cultivation sites' initial certification, spanning from 2014 to 2018. We also observed 1 consistency meeting in July 2018, and compared the Department's inspection procedures to best practices for implementing a regulatory program.[85] Additionally, to assess the Department's enforcement processes, we reviewed provider meeting agreements and plans of correction. Finally, to review the Department's oversight of infusion kitchens, we reviewed the State's food safety rules and food code, interviewed officials from Coconino County's Public Health Services District, and reviewed Coconino County's ordinance and rules and regulations related to infusion kitchens.

- To assess whether the Department appropriately investigated and adjudicated complaints, we reviewed a random sample of 30 of the 291 complaints submitted online between August 2015 and May 2018. We also reviewed all 6 complaints that were submitted to the Department via email between January 2017 and

[84] We observed 3 compliance inspections, 1 ATO inspection, and 1 complaint inspection.

[85] National State Auditors Association. (2004). *Carrying out a state regulatory program: A National State Auditors Association best practices document*. Lexington, KY.

October 2018. Additionally, we observed 1 complaint inspection in June 2018. Finally, we compared the Department's procedures to complaint-handling best practices.[86]

- To assess the Department's fee-setting process for registry identification cards and medical marijuana facilities, we reviewed the decision by the Arizona Court of Appeals, Division One, in *Daniels, et al. v. Arizona Department of Health Services, et al*., and best practices for government fee setting developed by several government and professional organizations.[87]

- To determine whether the Department used the Medical Marijuana Fund for permissible expenditures, we reviewed statute, rule, and Arizona Attorney General Opinion I18-009 to determine permissible uses of Fund monies under the Act. We also reviewed a fiscal year 2018 listing of employee salaries paid from the Fund and reviewed a judgmental sample of 65 of 7,177 fiscal year 2018 Fund expenditure transactions to determine if the Fund expenditures appeared permissible under the Act. In addition, we reviewed standards for spending monies in compliance with statutory and program requirements.[88]

- To obtain information for the Other Pertinent Information section of the report, we reviewed 3 compendia on state medical marijuana laws as well as other states' statutes and rules.[89] We also interviewed officials from the Colorado Department of Revenue; Colorado Department of Public Health and Environment; Nevada Department of Health and Human Services; Nevada Department of Taxation; Washington State Department of Health; and the Washington State Liquor and Cannabis Board.

- To determine whether the Department appropriately processed and evaluated dispensary registration certificate (DRC) applications, we judgmentally selected and reviewed 6 DRC applications from the 2016 DRC allocation process against statutory and rule requirements. We also recalculated the mapping results of the GIS mapping contractor for the 6 DRC applications we reviewed.

- To obtain additional information for the Introduction, we reviewed the Department's End of Year Reports for calendar years 2014 through 2018 to determine the number of qualifying patients with registry identification cards and the amount of medical marijuana sold. In addition, we compiled and analyzed information from the AFIS *Accounting Event Transaction File* and the *State of Arizona Annual Financial Report* for fiscal years 2016 through 2018 and Department-provided financial information for fiscal year 2019. Further, we reviewed changes to the provisions of the Act resulting from Laws 2019, Ch. 318.

- Our work on internal controls included reviewing the Department's policies and procedures and, where applicable, testing compliance with these policies and procedures. Additionally, we reviewed the reliability and accuracy of the Department's relevant information systems, such as the accuracy of information recorded in the Department's inspection database and complaint log. Where applicable, we also assessed the extent to which the Department documented its actions, such as documenting complaint investigations, and providing

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[86] NSAA, 2004; Commonwealth Ombudsman. (2009). *Better practice guide to complaint handling*. Canberra, Australia; New South Wales Ombudsman. (2015). *Complaint management framework*. Sydney, Australia; Queensland Ombudsman. (2006). *Effective complaints management: Guide to developing effective complaints management policies and procedures*. Brisbane, Australia.

[87] We reviewed the following fee-setting best practices: Arizona State Agency Fee Commission. (2012). *Arizona State Agency Fee Commission report*. Phoenix, AZ; Government Finance Officers Association. (2014). *Establishing government charges and fees*. Chicago, IL. Retrieved 1/29/2019 from https://www.gfoa.org/establishing-government-charges-and-fees; Government Finance Officers Association. (2002). *Full cost accounting for government services*. Chicago, IL. Retrieved 1/29/2019 from http://www.gfoa.org/full-cost-accounting-government-services; Michel, R.G. (2004). *Cost analysis and activity-based costing for government*. Chicago, IL: Government Finance Officers Association; Mississippi Joint Legislative Committee on Performance Evaluation and Expenditure Review. (2002). *State agency fees: FY 2001 collections and potential new fee revenues*. Jackson, MS; U.S. Government Accountability Office. (2008). *Federal user fees: A design guide*. Washington, DC; and U.S. Office of Management and Budget. (1993). *OMB Circular No. A 25, revised*. Washington, DC. Retrieved 3/7/2019 from https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.

[88] *State of Arizona Accounting Manual*; U.S. Government Accountability Office. (2014). *Standards for internal control in the federal government*. Washington, D.C.; 2 CFR 200.403, 2 CFR 200.404, and 2 CFR 200.430.

[89] National Alliance for Model State Drug Laws. (2017). *Marijuana: Comparison of state laws allowing use for medical purposes*. Manchester, IA. National Conference of State Legislatures. (n.d.). *State medical marijuana laws*. Retrieved 7/10/2018 from http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx. ProCon.org. (n.d.). *30 legal medical marijuana states and DC: Laws, fees, and possession limits*. Santa Monica, CA.

training to staff. We reported our conclusions on applicable internal controls and the Department's needed efforts to improve them in Findings 1 through 7.

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 that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Auditor General and staff express appreciation to the Department's Director and staff for their cooperation and assistance throughout the audit.

AGENCY RESPONSE

ARIZONA DEPARTMENT
OF HEALTH SERVICES

June 19, 2019

Ms. Lindsey Perry, Auditor General
Arizona Office of the Auditor General
2910 North 44th Street, Suite 410
Phoenix, Arizona 85018

Re: Medical Marijuana Program Performance Audit

Dear Ms. Perry:

The Arizona Department of Health Services ("Department") would like to thank you for the opportunity to respond to the recommendations and findings on the performance audit dated April 30, 2019. While the Department does not agree with every finding, we are committed to implementing those recommendations that will improve our department.

The Department has noted its agreement or lack thereof to each of the findings individually, in the prescribed attached format. The Department has a strong desire to constantly find a better way of performing our responsibilities through improved processes. We appreciate your work in helping us to improve and for the Auditor General's Office and its staff for its professionalism, consideration, and thoroughness during this process.

Sincerely,

Cara M. Christ, MD
Director

Finding 1: Department should take more timely action to revoke registry identification cards

Recommendation 1: The Department should develop and implement policies and procedures for revoking medical marijuana registry identification cards, including developing internal steps and associated time frames for revocation process steps that are within its control.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Department will develop policies and procedures to address the findings consistent with Arizona Management System, highlighting a streamlined process and customer service. ADHS is pleased that the Auditor General recognizes many of these processes and timeframes are outside the Department's control, however, ADHS also recognizes that internal processes can always be improved to deliver a more consistent result.

Recommendation 2: The Department should track and oversee performance for the time frames to ensure revocations occur as quickly and consistently as possible.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Department currently monitors various metrics to ensure performance across the program, specifically timeframes for the issuance of patient cards and licenses. ADHS agrees that in order to ensure timely revocations, a robust tracking system can be implemented to ensure timely revocations.

Finding 2: Some medical marijuana facility inspections not completed timely or consistently

Recommendation 3: The Department should develop and implement policies and procedures for its inspection processes to ensure Department staff apply, assess, and enforce statutory and rule requirements consistently during inspections. The policies and procedures should address: 1) how often inspections should be conducted; 2) how the Department will schedule and track inspections; 3) how to conduct the inspections, including how violations will be assessed; and 4) how to accurately maintain a record of its inspection process and results.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Department agrees with the Auditor General findings and will work to achieve the overall goal of improved tracking and improved survey consistency and training.

Recommendation 4: The Department should develop and implement a structured training program that comprehensively addresses the Program's inspection policies and procedures.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: A training program for surveyors for new and existing surveyors will be implemented to improve consistency.

Recommendation 5: The Department should continue holding and documenting consistency meetings between inspectors and Program management and, as appropriate, consult with its legal counsel regarding decisions reached at consistency meetings.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented

Response explanation: The Department is pleased with the Auditor General's findings and recommendation to continue an existing practice.

Finding 3: Department has inadequately investigated and monitored some complaints.

Recommendation 6: The Department should update and implement policies and procedures for its complaint-handling process, including:

- Determining and documenting whether complaints are in its jurisdiction.
- Determining when a secondary review of complaints is necessary to ensure complaints are appropriately assigned for investigation, such as mandating a secondary review for all complaints determined to be outside the Department's jurisdiction.
- Documenting all complaint investigation activities and any decisions reached from investigations.
- Establishing time frames for completing key steps of the complaint-handling process.
- Ensuring each complaint received by the Department is accurately recorded, tracked, and monitored in a complaint log or in another centralized location.
- Reviewing complaint outcomes and trends, and taking any necessary actions based on the trends identified.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: None.

Recommendation 7: The Department should develop and implement training for all staff involved in the complaint-handling process once it has developed the policies and procedures outlined in Recommendation 6, including training for new staff and periodic refresher training for all staff.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Department will implement a training program for new and existing employees improve the consistency and tracking of the complaint process.

Finding 4: Department has not consistently addressed medical marijuana facility noncompliance

Recommendation 8: The Department should develop and/or update and implement policies and procedures for addressing statutory and rule violations by medical marijuana facilities. These policies and procedures should include guidance for addressing medical marijuana facility noncompliance, such as when to seek a provider meeting and how to conduct provider meetings; the use of unannounced inspections; when to seek monetary penalties; when it should pursue revocation of a dispensary registration certificate; and where to document these decisions. Once these policies are developed and/or updated, all appropriate Program staff should be trained on these policies and procedures.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Department remains committed to working with our assistant attorney generals and our stakeholders to continuously evaluate how the Department can best address rule and statute violations by dispensaries. The Department will continue to maintain, update, and use our enforcement schedule to ensure consistency.

Finding 5: Although licensed as food establishments, Department does not inspect for food safety requirements at medical marijuana infusion kitchens

Recommendation 9: The Department should conduct unannounced food safety inspections of infusion kitchens on an ongoing basis, similar to its practices for other licensed food establishments in the State.

Department Response: The finding of the Auditor General is not agreed to and will not be implemented.

Response explanation: While the Department can appreciate the reasoning and recommendation of the Auditor General, the Department and legal counsel do not believe the statutory authority exists to conduct unannounced visits on food establishments located within a medical marijuana dispensaries.

Finding 6: Department should establish and implement process for setting Program fees

Recommendation 10: To help ensure medical marijuana fees reflect associated program costs, consistent with fee-setting models outlined in best practices, the Department should:

Recommendation 10a: Develop and implement a method, including associated policies and procedures, for determining the direct and indirect costs for providing the Program.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented

Response explanation: While the Department agrees with the finding and will implement internal processes to assess program costs and fees, it is worth noting that recent legislation has made significant changes to the program including doubling all card expiration timeframes, mandating a new medical marijuana testing certification and testing program and significant changes to the IT systems that are required to operate the program. The Department will take into account how the new legislation impacts the fees and program costs.

Recommendation 10b: After developing a cost methodology, determine whether the fees for medical marijuana registry identification cards and medical marijuana facilities should be modified to appropriately align with Program costs.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: None.

Recommendation 10c: If fee changes are appropriate, proceed with rulemaking to modify its fees, including seeking an exemption from the rulemaking moratorium as necessary and seeking input from stakeholders.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: None.

Recommendation 10d: Develop and implement a process to periodically reevaluate the fees associated with the Program.

Department Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Department believes that a good faith effort was used in determining fees related to expected, and unknown Program expenditures at the onset of the Program. However, the Department recognizes that more formal processes should be in place

Finding 7: Department misallocated some Medical Marijuana Fund monies

Recommendation 11: The Department should establish and implement written policies and procedures regarding the use of Fund monies that include the following: 1) the Program expenditures that are allowable under the Act; 2) how to allocate expenditures when more than 1 Department program benefits from the expenditure; 3) the processes and documentation necessary to charge payroll costs to the Fund to ensure it is only charged for

the work employees perform on the Program; 4) the type of supporting documentation that should be prepared and retained for all Fund expenditures; and 5) a description of monitoring activities, including any supervisory responsibilities, that will help ensure that Fund monies are being spent in accordance with the Act.

Department Response: The finding of the Auditor General is not agreed to but the recommendations will be implemented.

Response explanation: The Department believes that monies for the Fund were spent in an allowable manner, and that payroll costs for the Fund were only charged for work employees performed on the Program. However, the Department recognizes that more formal processes should be in place.

Recommendation 12: The Department should continue using its required approval plan to help ensure that Fund monies are appropriately approved and accounted for.

Department Response: The finding of the Auditor General is agreed to and will be implemented.

Response explanation: The Department believes that monies for the Fund were approved of and accounted for in an accurate manner. However, the Department recognizes that more formal processes should be in place.


ARIZONA
Auditor General
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