Minnesota Department of Health
Office of Medical Cannabis

Internal Controls and Compliance Audit
July 2016 through December 2018

January 2020

Financial Audit Division

OFFICE OF THE LEGISLATIVE AUDITOR

STATE OF MINNESOTA

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OFFICE OF THE LEGISLATIVE AUDITOR
STATE OF MINNESOTA • James Nobles, Legislative Auditor

January 2020

Members
Legislative Audit Commission

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Minnesota Department of Health

This report presents the results of our internal controls and compliance audit of the Office of Medical Cannabis for the period July 2016 through December 2018. The objectives of this audit were to determine if the department had adequate internal controls over selected activities and complied with significant legal requirements.

This audit was conducted by Valerie Bombach (Audit Director), Todd Pisarski (Auditor-in-Charge), and Kelsey Carlson (Senior Auditor).

We received the full cooperation of the Minnesota Department of Health's staff while performing this audit.

Sincerely,

Valerie Bombach
Audit Director

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L'ETOILE DU NORD
1858

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Report Summary

Minnesota is one of 33 states that allows qualifying patients the legal access to medical cannabis for health care treatment. Derived from the cannabis plant, medical cannabis has been reported to help treat some illnesses and symptoms.

The Minnesota Department of Health (MDH) oversees Minnesota's medical cannabis program and must ensure that participants and medical cannabis manufacturers comply with eligibility, payment, and other legal requirements. In Fiscal Year 2019, 17,200 patients were enrolled in the program, and MDH expenditures totaled $1.57 million.

The Office of the Legislative Auditor conducted this audit to determine whether MDH had adequate internal controls and complied with significant legal requirements. The audit scope included MDH's oversight of patient eligibility, participating health care practitioners, and fee revenues. We also examined the department's oversight of manufacturer and laboratory processes to ensure a tested and reliable supply of medical cannabis for patients. Our work did not include a comprehensive audit of medical cannabis manufacturers and laboratories or their compliance with legal requirements. The period we examined was from July 1, 2016, through December 31, 2018.

Conclusions

Internal Controls

OLA found that the Minnesota Department of Health's internal controls were generally not adequate to safeguard financial assets and ensure compliance with selected legal requirements for the medical cannabis program.

Internal Controls

We identified the following weaknesses in internal controls related to authorizing participants, processing fees, tracking and testing medical cannabis, and preventing and detecting diversion of the drug. We discuss these more thoroughly in the findings and recommendations in the report.

- Finding 1. The Minnesota Department of Health did not verify for all new patients that the license of their health care practitioner was active and in good standing. (p. 11)

- Finding 2. The Minnesota Department of Health did not keep valid documentation of the eligibility of parents or legal guardians for the medical cannabis program. (p. 12)

- Finding 4. The Minnesota Department of Health did not adequately reconcile some medical cannabis patient fees or ensure employee separation of duties when handling these payments. (p. 17)

- Finding 5. The Minnesota Department of Health did not ensure that each of the two medical cannabis manufacturers had a formal contract with a testing laboratory. (p. 19)

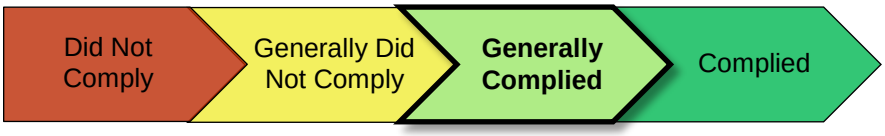
- Finding 6. The Minnesota Department of Health did not have adequate controls to ensure manufacturers accurately tracked and tested medical cannabis prior to sale. (p. 20)

- Finding 7. The Minnesota Department of Health did not have adequate controls to help prevent and timely detect diversion or loss of medical cannabis by a manufacturer. (p. 22)

Legal Compliance

The Minnesota Department of Health generally complied with most legal requirements that we tested, although we noted some exceptions related to the authorization of health care practitioners, some fee payments, and manufacturer contracts.

Legal Compliance



OLA found the following issues of noncompliance, discussed more thoroughly in the findings and recommendations in this report.

- Finding 1. The Minnesota Department of Health did not verify for all new patients that the license of their health care practitioner was active and in good standing. (p. 11)

- Finding 3. The Minnesota Department of Health charged some medical cannabis patients a lower registration fee than permitted in state statutes. (p. 16)

- Finding 5. The Minnesota Department of Health did not ensure that each of the two medical cannabis manufacturers had a formal contract with a testing laboratory. (p. 19)

Audit Overview

This report presents the results of an internal controls and compliance audit of selected activities in the Minnesota Department of Health (MDH). Management is responsible for establishing internal controls to safeguard assets and ensure compliance with applicable laws, regulations, and state policies.

A strong system of internal controls begins with management's philosophy, operating style, and commitment to ethical values. It also includes processes to continuously assess risks and implement control activities to mitigate risks. A successful internal controls system includes iterative processes to monitor and communicate the effectiveness of control activities.

Background

Medical cannabis is derived from the cannabis plant and has been reported to potentially help treat some illnesses and symptoms.

Minnesota is one of 33 states that allows qualifying health care patients the legal access to medical cannabis. Minnesota law passed in 2014 directed MDH to establish a new medical cannabis "Patient Registry Program" for this purpose.[1] As part of its duties, MDH must collect and evaluate data from the program and report to the Minnesota Legislature the benefits, risks, and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis.[2]

Medical Cannabis:

- Includes any species, mixture, or preparation of the cannabis plant.
- Is administered in the form of liquid or pill, vaporized with the use of oil or liquid, or other form approved by MDH.
- Does not involve the use of dried leaves or plant form and may not be smoked.

— *Minnesota Statutes* 2019, 152.22, subd. 6(a) 1-4.

[1] *Laws of Minnesota* 2014, chapter 311, codified as *Minnesota Statutes* 2014, 152.22-152.37. Through the remainder of this report, we refer to the program as the medical cannabis program.

[2] *Minnesota Statutes* 2019, 152.27, subds. 1(a) and 2(a)(7).

Internal controls are particularly important for the state's medical cannabis program due to the federal classification of marijuana as a Schedule I controlled substance and the risk of its diversion for unauthorized purposes.[3] Federal regulations also prohibit the transport of medical cannabis across state lines.[4] To address these risks, Minnesota statutes direct MDH to register and oversee two "in-state" medical cannabis manufacturers in their production and distribution of medical cannabis.[5] The department also oversees other program participants and functions.

Diversion:

The intentional transfer of medical cannabis to a person other than another registered manufacturer, a patient, a registered designated caregiver, or a registered parent, legal guardian, or spouse of a patient.

***— Minnesota Statutes* 2019, 152.33, subd. 1.**

Roles and Responsibilities

Department of Health – Office of Medical Cannabis

The Office of Medical Cannabis (OMC) administers the medical cannabis program.[6] Exhibit 1 summarizes key roles and responsibilities for OMC and program participants. For example, OMC must provide to potential health care practitioners information on program requirements and the therapeutic use of medical cannabis, allow qualifying practitioners to participate, and supervise their compliance with patient treatment requirements.[7]

OMC also oversees the patient enrollment processes, verifies the eligibility of designated caregivers for patients, and collects patient registration fees.[8] However, the department may deny a patient who was previously removed from the program for a qualifying violation or if they provided false information.[9]

State statutes also direct the department to adopt rules and procedures for the enforcement of legal requirements for the program.[10] For example, OMC must notify law enforcement whenever there is sufficient cause to believe there is a threat to public safety, which includes diversion or potential diversion of medical cannabis by any manufacturer or participant in the program.[11] OMC publishes its procedures in its *OMC Regulatory & Enforcement Plan*, which outlines controls over program compliance, enforcement processes, and remedies to resolve and correct any noncompliance by participants or manufacturers.

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[3] 21 *U.S. Code*, sec. 812(c) (2011); and *Minnesota Rules*, 4770.4002, subp. 4, published electronically June 20, 2016.

[4] 21 *U.S. Code*, sec. 841(a) (2019).

[5] *Minnesota Statutes* 2014, 152.25, subd. 1.

[6] *Minnesota Statutes* 2019, 152.27, subd. 1(a). *Minnesota Statutes* 2019, 152.26, grants the commissioner the authority to adopt rules to oversee the medical cannabis program.

[7] *Minnesota Statutes* 2019, 152.27, subd. 2(a) (1)-(6).

[8] *Minnesota Statutes* 2019, 152.27, subds. 3 and 4; and 152.35(a).

[9] *Minnesota Statutes* 2019, 152.27, subd. 6.

[10] *Minnesota Statutes* 2019, 152.261.

[11] *Minnesota Rules*, 4770.0300, subp. 2, published electronically June 20, 2016.

Exhibit 1: Medical Cannabis Program, Key Roles and Responsibilities

Office of Medical Cannabis (OMC)

- Explain program requirements and therapeutic uses of medical cannabis.
- Enroll and oversee health care practitioners providing treatment to participating patients.
- Verify and enroll qualifying patients, designated caregivers, parents, legal guardians, and spouses.
- Collect annual registration fees from patients and registered medical cannabis manufacturers.
- Examine the business and financial affairs, practices, and conditions of the medical cannabis manufacturers.

Health Care Practitioners (HCP)

- Determine if a patient suffers from a qualifying condition; provide the patient with a certification of diagnosis.
- Determine whether a patient is disabled and requires assistance to administer or obtain medical cannabis.
- Provide patient's health records to MDH on an ongoing basis.

Patients

- Complete and submit the application and annual registration fee.
- Agree to receive regular treatment for the qualifying condition from a designated HCP.
- Designate a caregiver (if certified by HCP as disabled and needing assistance to administer or obtain medical cannabis).

Parents, Legal Guardians, Spouses, and Designated Caregivers

- Agree to possess medical cannabis for the purposes of assisting the patient.
- Undergo a background check by the Bureau of Criminal Apprehension (designated caregivers only).
- Serve as the patient's registered caregiver to help the patient administer and obtain medical cannabis.
- Notify OMC within 30 days of any change in patient information and within 10 days of a patient's death.
- Dispose of unused medical cannabis within 10 days of the patient leaving the program.

Registered Medical Cannabis Manufacturers

- Provide a reliable and ongoing supply of medical cannabis for the patients in the Patient Registry Program.
- Cultivate, produce, and distribute medical cannabis in an allowable form within the state.
- Contract with a laboratory to test medical cannabis produced.
- Assign a tracking number to any medical cannabis distributed and ensure accurate record keeping.
- Ensure dispensary pharmacists have a current license issued by the Minnesota Board of Pharmacy.
- Enact security measures to deter and prevent the diversion or theft of medical cannabis.
- Report monthly to OMC any medical cannabis distributed to each patient including the dosages, chemical composition, and tracking number assigned to the medical cannabis.

Independent Laboratories

- Demonstrate its eligibility to perform required testing.
- Test medical cannabis in the allowed deliverable form for content, contamination, and stability.

SOURCES: *Minnesota Statutes* 2019, 152.25, subd. 1(e); 152.27; 152.28, subd. 1; 152.29; 152.30; 152.35 (a) and (c); 152.37, subd. 3; *Minnesota Rules,* 4770.1900, subp. 2, published electronically September 7, 2018; *Minnesota Rules,* 4770.2700, subp. A, published electronically February 20, 2015; and *Minnesota Rules,* 4770.4008, subps. A and B, published electronically July 7, 2015.

Program Participants

Health care practitioners, patients, designated caregivers, parents, legal guardians, and spouses must comply with certain requirements to remain eligible to participate in the program. For example, health care practitioners determine whether a patient suffers from a qualifying condition and, if so, provides the patient with a certification annually of that diagnosis.[12] The practitioner also determines and certifies annually whether the patient is developmentally or physically unable to acquire or self-administer the medical cannabis and may need a designated caregiver.[13]

A designated caregiver agrees to possess medical cannabis in order to assist the patient.[14] A designated caregiver must apply to MDH and obtain a background check, although a parent or legal guardian may serve in this role without having to register as a caregiver.[15] A designated caregiver also must notify OMC within 30 days of any change in required patient information, provide notice to OMC within 10 days of a patient's death, and properly dispose of any unused medical cannabis within 10 days of the patient leaving the program.[16]

Medical Cannabis Manufacturers

On December 1, 2014, MDH approved and registered two in-state manufacturers—LeafLine Labs, LLC, and Minnesota Medical Solutions, LLC—to cultivate, produce, and dispense medical cannabis within Minnesota. Each manufacturer must provide a reliable and ongoing supply of medical cannabis for program patients, process any medical cannabis plant material into an allowable form, and assign a tracking number to its product prior to its distribution.[17] Through their pharmacy dispensaries, each manufacturer also must ensure that licensed pharmacists verify the identity and eligibility of patients and designated caregivers, parents, or legal guardians if they are picking up a prescription for the patient.[18]

Exhibit 2 illustrates the service regions and locations for these two manufacturers to dispense medical cannabis in Minnesota, as of July 2019. Each manufacturer was limited to one manufacturing location and four regions within which it must operate a dispensary.[19]

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[12] *Minnesota Statutes* 2019, 152.28, subd. 1(a)(1) and (b)(3).

[13] *Minnesota Statutes* 2019, 152.28, subd. 1(a)(2).

[14] *Minnesota Statutes* 2019, 152.27, subd. 4(a)(2).

[15] *Minnesota Statutes* 2019, 152.27, subds. 4(b) and 5.

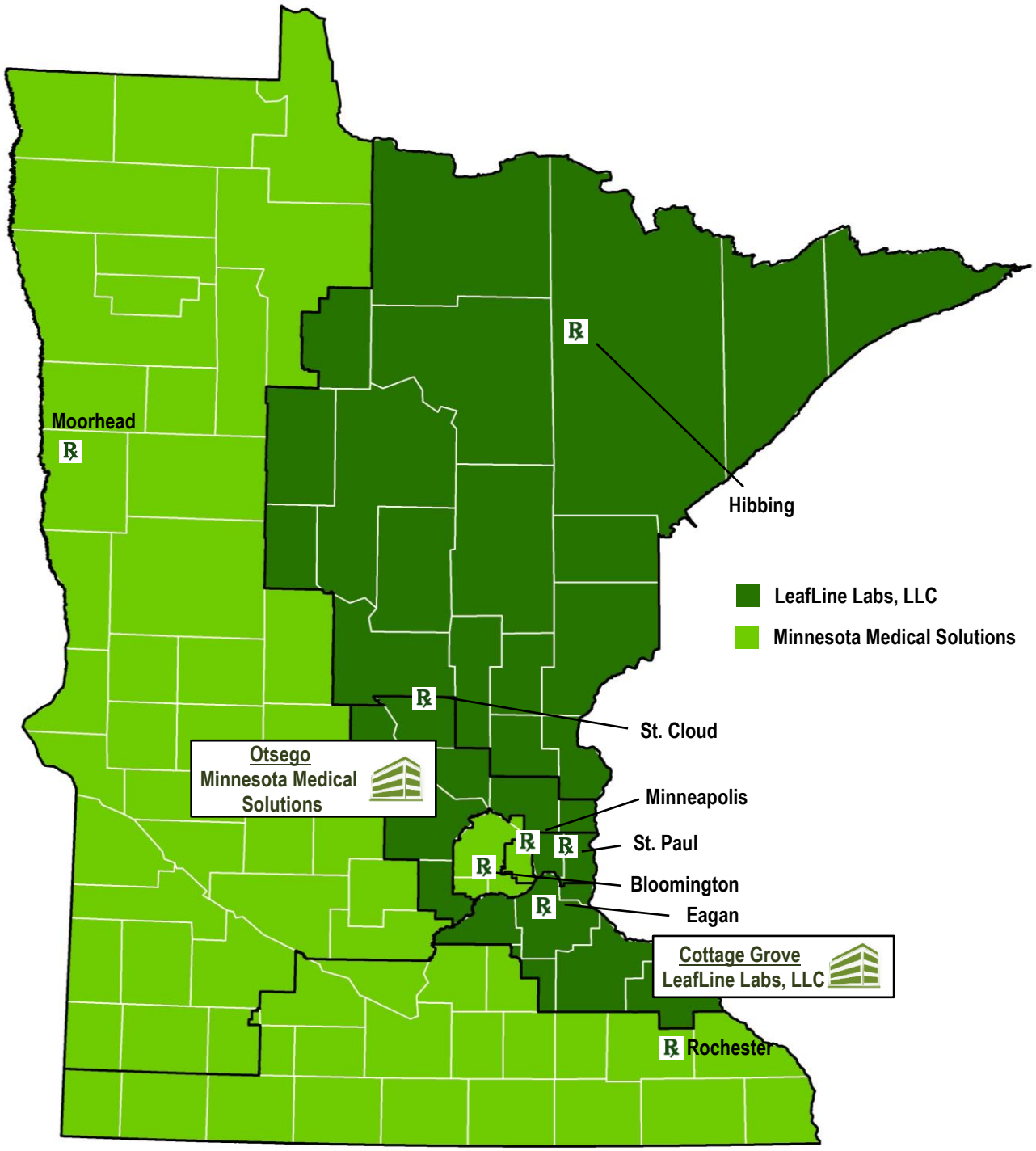
[16] *Minnesota Rules*, 4770.4008, sec. A, published electronically July 7, 2015.

[17] *Minnesota Statutes* 2019, 152.29, subds. 2 and 3(c)(3).

[18] *Minnesota Statutes* 2019, 152.29, subd. 3(a) and (c)(1) - (2).

[19] *Minnesota Statutes* 2018, 152.29, subd. 1(a). The statute was amended in 2019 to require each manufacturer to operate eight distribution facilities.

Exhibit 2: Minnesota Medical Cannabis Manufacturers and Dispensary Locations, by Service Area, July 2019



SOURCE: Office of the Legislative Auditor.

Independent Laboratories

Minnesota statutes require that each of the two manufacturers contract with a qualified laboratory approved by OMC to test their medical cannabis products for various elements, such as content, contamination, and stability.[20] In April 2015, OMC approved two laboratories—Aspen Research Corporation and Legend Technical Services, Inc.—and has annually reapproved these entities to test medical cannabis for the program.

Audit Scope, Objectives, Methodology, and Criteria

We audited MDH's internal controls and compliance with selected legal requirements for the medical cannabis program during the period of July 1, 2016, through December 31, 2018. We focused on the design and implementation of MDH's internal controls to (1) ensure that only eligible patients had access to medical cannabis; (2) collect and safeguard fees from the program; (3) ensure a tested and reliable supply of medical cannabis; and (4) prevent and timely detect potential diversion of the drug for unauthorized purposes. Our scope did not include internal controls or legal compliance by the manufacturers or testing laboratories.

Authorize Program Participants

We designed our work to address the following questions:

- Did MDH have adequate controls to verify that enrolled patients, health care practitioners, parents, legal guardians, and designated caregivers were eligible to participate in the medical cannabis program?

- Did MDH comply with significant legal requirements related to participant eligibility for the medical cannabis program?

To answer these questions, we interviewed staff from the Office of Medical Cannabis to understand the enrollment and verification processes for patients, health care practitioners, parents, legal guardians, and designated caregivers. We reviewed federal and state laws and rules and MDH policies governing the program. To understand MDH's Medical Cannabis Registry (MCR) information system and the process for recording and reporting the sale of medical cannabis, we interviewed staff and reviewed information from MDH, LeafLine Labs, and Minnesota Medical Solutions. We also obtained data from the MCR system and reviewed a sample of 90 patients and 40 health care practitioners to test the effectiveness of OMC's internal controls and MCR system controls to confirm participants' eligibility for the program.

[20] *Minnesota Statutes* 2019, 152.29, subd. 1(c); and *Minnesota Rules*, 4770.1900, subps. 2 and 2A, published electronically September 7, 2018.

Collect and Safeguard Patient Fees

We designed our work to address the following questions:

- Did MDH have adequate financial-related controls over the medical cannabis program?
- Did MDH impose the correct patient registration fees and properly secure, record, and deposit receipts for the medical cannabis program in accordance with legal and administrative requirements?

To answer these questions, we reviewed Minnesota statutes, Minnesota Management and Budget operating policies for state agencies, and MDH internal policies and procedures. We interviewed MDH and OMC staff responsible for processing electronic and manual financial transactions and fee payments. Using data from the state's accounting system (SWIFT) and OMC's Patient Registry, we performed a reconciliation of patient registration fees received for the period July 1, 2016, through December 31, 2018. We also tested a sample of 90 financial transactions to verify how OMC determines eligibility and applies the patient registration fee.

Ensure a Tested and Reliable Supply of Medical Cannabis and Prevent and Detect Diversion

We designed our work to address the following questions:

- Did MDH have adequate controls to ensure that the manufacturers complied with significant legal requirements for testing and tracking medical cannabis and to prevent and detect diversion of the drug?
- Did MDH comply with significant legal requirements related to the testing and distribution of medical cannabis for the program?

To answer these questions, we reviewed federal and state laws and rules governing the cultivation, production, and distribution of medical cannabis. We also interviewed representatives from OMC, LeafLine Labs, Minnesota Medical Solutions, and the independent laboratories that test medical cannabis sold through the program; we also conducted on-site visits of these facilities. To understand the processes for tracking, recording, and reporting the sale of medical cannabis, we interviewed staff, reviewed information, and analyzed data from MDH and the medical cannabis manufacturers.

To understand the internal controls to prevent and detect diversion, we observed OMC staff conduct an unannounced inspection at each of the manufacturers and, as part of this inspection, inventoried their product to test the manufacturer's compliance with OMC and legal requirements. We also reviewed certain documents and reports required in law regarding the tracking of medical cannabis produced and sold under the program. Finally, we reviewed any compliance actions OMC conducted during the audit period and compared OMC enforcement actions to its internal control procedures for oversight of the manufacturers.

We conducted this performance audit in accordance with generally accepted government auditing standards.[21] 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.

We assessed internal controls against the most recent edition of the internal control standards, published by the U.S. Government Accountability Office.[22] To identify legal compliance criteria for the activity we reviewed, we typically examine state and federal laws, state administrative rules, state contracts, and policies and procedures established by the departments of Management and Budget and Administration.

[21] Comptroller General of the United States, Government Accountability Office, *Government Auditing Standards* (Washington, DC, December 2011).

[22] Comptroller General of the United States, Government Accountability Office, *Standards for Internal Control in the Federal Government* (Washington, DC, September 2014). In September 2014, the State of Minnesota adopted these standards as its internal control framework for the executive branch.

Authorize Program Participants

The Minnesota Department of Health's Office of Medical Cannabis (OMC) must enroll health care practitioners and verify that individuals are qualified to participate in the medical cannabis program.[23] These processes help prevent unauthorized access to medical cannabis or diversion of the drug for other purposes.

We concluded that the department had generally adequate controls to authorize participants for the program, but found exceptions in its processes to verify (1) that participating health care practitioners had valid licenses after their initial enrollment, and (2) the relationship of a parent or legal guardian with the patient.

Verify Health Care Practitioner License

The Office of Medical Cannabis validates that a physician, physician's assistant, or advanced practice registered nurse may participate in the program.[24] Specifically, OMC requires each practitioner to provide background information and a valid medical license number so that OMC staff can verify the data with the Minnesota Board of Medical Practice or respective licensing board.

FINDING 1

The Minnesota Department of Health did not verify for all new patients that the license of their health care practitioner was active and in good standing.

MDH lacked adequate processes to approve health care practitioners for the program because OMC staff only reviewed a practitioner's medical license upon initial application. OMC staff told us that they do not reverify this information when the department enrolls a new patient for the same practitioner or upon annual patient renewal. This initial, one-time license review is not sufficient to identify health care practitioners whose licenses subsequently expired or lapsed. An OMC representative told us that staff do periodically review reports of disciplinary actions from each of the licensing boards and inactivate practitioners whose licenses are restricted to prevent their future participation in the program. However, Minnesota rules do not require health care practitioners to notify the department of a change in license status, further compounding the risk.

[23] *Minnesota Statutes* 2019, 152.27, subds. 2(a) and 3-6; and Minnesota Department of Health, Office of Medical Cannabis, *OMC Regulation-Enforcement Plan*, v1.3, April 2018, 38.

[24] *Minnesota Rules*, 4770.4014, subp. 1(A), published electronically June 20, 2016, requires that, "The commissioner must accept written certifications for the therapeutic use of medical cannabis only from health care practitioners who hold…an active license, in good standing…."

We examined OMC's process to verify a health care practitioner's license and found that, for 2 of 40 samples (5 percent) of participating practitioners listed as active in the OMC registry, the information in the OMC registry did not align with information in the licensing board.[25] For one of these samples, the practitioner's license was expired and inactivated by the licensing board after OMC's initial approval.[26] For the other sample, the incorrect license number was entered into OMC's registry and did not match the name of the practitioner. Despite this discrepancy, it appeared that OMC approved the correct practitioner for the program.

RECOMMENDATIONS

The Minnesota Department of Health should:

- **Verify that a health care practitioner's license is active and in good standing when the department approves a new patient for the medical cannabis program, as required by state statute.**
- **Amend the Minnesota Department of Health's rules to require a health care practitioner to notify the department of a change in license status or when discontinuing care for patients in the program.**

Validate Caregiver Relationship with Patient

State statutes and MDH rules require a caregiver to provide MDH with assurances of their qualifications so that MDH may approve their enrollment in the program.[27] For example, a parent or legal guardian of a patient must provide proof of their identity and relationship to the patient to MDH.[28]

FINDING 2

The Minnesota Department of Health did not keep valid documentation of the eligibility of parents or legal guardians for the medical cannabis program.

MDH lacks adequate controls to confirm the eligibility of parents or legal guardians for the medical cannabis program due to system limitations within the Medical Cannabis

[25] We tested the licenses of 40 of 852 health care practitioners who were enrolled in the medical cannabis program and were listed in the OMC patient registry as having active licenses in good standing.

[26] The one sample practitioner whose license had expired was no longer treating medical cannabis patients.

[27] *Minnesota Statutes* 2019, 152.27, subds. 4 and 5; and *Minnesota Rules*, 4770.4007, subp. 1, published electronically July 7, 2015. Minnesota statutes were amended in 2019 to allow an eligible spouse to act as a caregiver.

[28] Minnesota Department of Health, *OMC Regulation-Enforcement Plan*, 42. *Minnesota Rules*, 4007.4005, subp. 1(B), published electronically July 7, 2015, requires that, if a patient is a minor, a parent or legal guardian must provide proof of their Minnesota residency.

Registry and weak OMC documentation standards. Specifically, the patient registry can hold only two documents for this verification task. If a parent or legal guardian uploads a third document into the system, the registry will remove the oldest document and replace it with the new document. The registry also does not have an event log to record documents previously loaded into the system.

We examined OMC's verification of parents and legal guardians and, for 4 out of 25 sample cases (16 percent) that we tested, we could not verify that OMC obtained valid documents to confirm a relationship between the caregiver and the patient.[29] For the samples we tested, a parent or legal guardian may have provided the required documents. However, neither we nor OMC staff could confirm whether the evidence was received, adequate, or required follow-up.

Failure to request and keep appropriate documents that establish the parent or legal guardian relationship with a patient could allow for unauthorized access or diversion of medical cannabis.

RECOMMENDATIONS

The Minnesota Department of Health should:

- **Comply with department policy and ensure that a parent or a legal guardian provides valid, original documents that establish the relationship with the patient.**
- **Continue to work with Minnesota IT Services to improve the storage capacity of the Medical Cannabis Registry.**

[29] We tested OMC's verification for 25 of a total 2,036 parents and legal guardians who were enrolled in the medical cannabis program.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Collect and Safeguard Patient Fees

In Fiscal Year 2019, MDH expenditures for the medical cannabis program totaled about $1.57 million, as shown in Exhibit 3. The medical cannabis program is supported through appropriations and also fees paid by manufacturers and patients, which are deposited into the state's special revenue fund.[30] Patients must pay an initial enrollment and annual fee, and the two manufacturers must pay fees that help cover the cost of MDH oversight and inspections. During fiscal years 2017 through 2019, 22,819 patients were enrolled in the program.

We found that OMC did not collect the correct fee amounts from some patients and did not have adequate controls over the processing and reconciliation of fee payments.

Exhibit 3: Total Medical Cannabis Program Patients, Revenues, Appropriations, and Expenditures, Fiscal Years 2017-2019

	Fiscal Years			
Program	2017	2018	2019	Total
Total Patients	6,184	10,738	17,202	22,819[a]
Fee Revenues[b]				
Patient Registration Fee	$ 802,500	$1,414,500	$2,168,451	$4,385,201
Manufacturer Regulatory Fees	387,000	294,010	292,000	973,010
Total Revenues	$1,189,250	$1,708,510	$2,460,451	$5,358,211
Total General Fund and Special Revenue Fund Appropriations to MDH	$1,437,000	$1,907,000	$1,922,000	$5,266,000
Program Expenditures				
Payroll	$ 990,301	$1,042,956	$1,078,089	$3,111,346
Purchased Services	243,800	418,471	273,245	935,516
All Other Expenditures	176,593	222,115	219,973	618,680
Total Expenditures	$1,410,693	$1,683,542	$1,571,307	$4,665,543

[a] Total represents an unduplicated count of patients for all fiscal years 2017 through 2019. Some patients were enrolled in more than one year and, thus, total does not represent a sum of all years.

[b] Patient registration and manufacturer regulatory fees are deposited into the state treasury and credited to the state government special revenue fund.

SOURCE: State of Minnesota accounting system (SWIFT).

[30] *Minnesota Statutes* 2019, 152.35 (a) and (c).

Collect Correct Fee Amounts

State statutes define fee rates that MDH must collect from patients for the medical cannabis program. Most patients must pay a $200 enrollment fee, however, the fee is reduced to $50 if the patient receives Social Security disability or Supplemental Security Insurance payments or is enrolled in medical assistance or MinnesotaCare.[31]

FINDING 3

The Minnesota Department of Health charged some medical cannabis patients a lower registration fee than permitted in state statutes.

MDH extended the $50 reduced fee to patients who met criteria not defined in state statutes, including disabled veterans or enrollees in the federal Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA).[32] We examined OMC's collection of patient enrollment fees and found that OMC incorrectly charged the reduced $50 fee for 25 of 28 sample payments from patients who OMC identified as a disabled veteran. We estimated that these types of fee rate errors resulted in about $136,800 in lost revenue for the period July 1, 2016, through December 31, 2018.

We also tested the registration fees for all patients who paid by cash and check and found that, for 2 of 40 patient samples (5 percent), OMC incorrectly charged the $50 reduced fee rather than the required $200 fee.[33] These two patients had reached full retirement age and received Social Security retirement benefits (a status not eligible for the reduced fee) and, thus, were no longer entitled to Social Security disability.

For purposes of the medical cannabis program and patient enrollment fees, Minnesota statutes do not give MDH authority to add other qualifying criteria or assistance programs or otherwise revise the fee schedule.

RECOMMENDATIONS

- **The Minnesota Department of Health should comply with state statutes and collect the correct fees from patients in the medical cannabis program.**
- **The Legislature should consider whether disabled patients who receive Social Security retirement benefits should pay a reduced medical cannabis fee and amend state statutes accordingly.**

[31] *Minnesota Statutes* 2019, Chapter 152.35 (a).

[32] *Minnesota Statutes* 2019, 152.35 (a). OMC staff told us they believe disabled veterans meet the criteria "enrolled in medical assistance or MinnesotaCare" and are eligible for reduced fees.

[33] We tested the registration fees of 40 of all 763 patients who paid a reduced fee between July 1, 2016, and December 31, 2018.

Safeguard Registration Fees

Some medical cannabis patients are unable to complete their applications electronically online and, instead, submit a paper application and pay the registration fee using a check or cash. OMC staff must then manually transfer information into the registry and process the payments.

In November 2017, the Minnesota Department of Health conducted an agency-wide internal audit for fee receipts, the results of which included findings on OMC's policies and processing of fee payments. As part of OLA's audit work, we followed up on the MDH audit findings.

FINDING 4

The Minnesota Department of Health did not adequately reconcile some medical cannabis patient fees or ensure employee separation of duties when handling these payments.

MDH did not resolve prior audit findings regarding weaknesses in internal controls over fee collections. For our audit period, OMC was unable to fully reconcile fee revenue between the program's internal accounting records and the state's accounting system.[34] This inability to reconcile fees was due to technical limitations in the Payment Registry, which only has functionality to record electronic payments. For patient registration fees paid by cash or check—totaling $151,000 during our audit scope—OMC reconciled fee revenue within their accounting records but did not verify payments against records in the Patient Registry. Reconciling deposits in the state treasury to the detailed patient accounting records is a key control to detect errors and irregularities.

OMC also did not resolve separation of duties issues that were reported by MDH auditors. OMC staff told us that, as a small office, turnover and keeping sufficient staffing is a struggle, and sometimes employees must fill multiple roles.

Minnesota Management and Budget policy directs state agencies to avoid the practice of assigning an employee multiple payment processing roles and to perform monthly reconciliations of receipts.[35]

RECOMMENDATION

The Minnesota Department of Health should comply with state policy and perform monthly reconciliations and ensure separation of employee duties when registering patients and processing fee payments for the medical cannabis program.

[34] We performed a reconciliation between OMC's check log and SWIFT and found that the overall monetary amounts materially matched (noting a $52 difference) for the period we reviewed.

[35] MMB Statewide Operating Policy 0602-01 states, "Agencies must develop internal policies and procedures to ensure that receipts are properly safeguarded, deposited and recorded in the state's accounting system…and that adequate separation of duties exists."


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Tested and Reliable Supply of Medical Cannabis

The Office of Medical Cannabis oversees the two manufacturers approved to cultivate, produce, and distribute medical cannabis for Minnesota's program. We examined the processes, inventory systems, and reporting requirements for manufacturers to accurately record the production, testing, and sale of medical cannabis.

We concluded that OMC did not have adequate controls to (1) ensure medical cannabis was tested by a laboratory before manufacturers dispensed it to patients, and (2) timely detect diversion of the drug.

Contract with a Laboratory

MDH must ensure that each of the two registered manufacturers has a contract with an approved independent laboratory to test medical cannabis for content, contamination, and stability.[36] The manufacturers also must provide a reliable and ongoing supply of medical cannabis needed for the program.[37]

FINDING 5

The Minnesota Department of Health did not ensure that each of the two medical cannabis manufacturers had a formal contract with a testing laboratory.

In April 2015, MDH approved two laboratories—Aspen Research Corporation and Legend Technical Services, Inc.—and has annually reapproved these entities to test medical cannabis for the program. These entities have performed such testing. However, Minnesota Medical Solutions did not have a formal contract with either laboratory until July 2018, and LeafLine Labs did not have a formal contract until May 2019, after we began our audit. OMC did not sanction either of the manufacturers for their lack of compliance with this legal requirement.[38]

In response to our inquiries regarding the lack of formal contracts, representatives from OMC, manufacturers, and laboratories told us that a formal contract for these testing

[36] *Minnesota Statutes* 2019, 152.25, subd. 1(e); and 152.29, subd. 1(c).

[37] *Minnesota Statutes* 2019, 152.29, subd. 2.

[38] *Minnesota Statutes* 2019, 152.25, subd. 1b, states that, "The commissioner may institute proceedings to temporarily suspend the registration of a medical cannabis manufacturer…if any action by…[the] manufacturer violates" statutory or regulatory requirements of the program. *Minnesota Statutes* 2019, 152.33, subd. 6, states that "a manufacturer shall be fined up to $1,000 for any violation" related to the statutory or regulatory requirements under the program.

services is unusual, and they instead rely on the laboratories' "chain of custody" testing forms for this purpose.

Testing the medical cannabis helps identify contaminants and ensures that the end product contains the appropriate dosage as prescribed by a pharmacist for a patient. The lack of a formal written contract and vague legal requirements impede the state's ability to hold manufacturers accountable for insufficient testing and take corrective action, if merited, for adverse reactions by patients who use medical cannabis dispensed through the program.[39]

RECOMMENDATION

The Minnesota Department Health should comply with state statutes and ensure that each of the registered manufacturers maintains a contract with an independent laboratory for purposes of testing medical cannabis.

Track the Testing and Sale of Medical Cannabis

Each medical cannabis manufacturer must assign and report to OMC unique identifying numbers of its product to help facilitate inventory tracking of medical cannabis from its cultivation through production, testing, and sale to a patient.[40] For example, each manufacturer must submit a monthly report to OMC that includes information about medical cannabis that was distributed to each patient, including the amount, dosage, chemical composition, and the tracking number assigned to the drug.[41] A tracking number helps ensure a product has been adequately tested prior to dispensing, allows for follow-up in the event of a patient's adverse drug reaction, and facilitates inventory accounting to prevent and detect diversion of medical cannabis for illegal purposes.

FINDING 6

The Minnesota Department of Health did not have adequate controls to ensure manufacturers accurately tracked and tested medical cannabis prior to sale.

Unlike medical cannabis programs in some other states, Minnesota does not use a single "seed-to-sale" reporting and inventory system that identifies and tracks a medical cannabis product from the point of cultivation through testing and sale to a patient. Instead, Minnesota relies on multiple reporting and recordkeeping mechanisms to track medical cannabis products.

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[39] *Minnesota Statutes* 2019, 152.25, subd. 1(e); and 152.29, subd. 1(c), do not require the manufacturer or the laboratory to notify OMC if they alter their contract.

[40] *Minnesota Statutes* 2019, 152.29, subd. 4(c); and *Minnesota Rules*, 4770.1700, subp. 1(H) (J), published electronically June 20, 2016, which requires that at the time of planting, all plants must be tracked in a batch process with a unique batch number that must remain with the batch through final packaging. The batch number must be displayed on the label of the medical cannabis.

[41] *Minnesota Statutes* 2019, 152.29, subd. 4(c).

We found that we—and OMC—could not independently track and verify in the Medical Cannabis Registry that a medical cannabis product was tested prior to its sale, for several key reasons. First, the medical cannabis program relies on different information systems used by OMC, the manufacturers, and the laboratories. Second, the manufacturers do not assign and use a single unique identifier to track a specific medical cannabis product from cultivation through testing and point of sale. Third, OMC does not collect complete inventory data from the manufacturers and laboratories and does not verify whether the data are accurate.[42] Lastly, we found data entry errors and omissions in the Medical Cannabis Registry.[43]

We also tested whether we could better track medical cannabis with more data from the manufacturers. We obtained directly from LeafLine Labs and Minnesota Medical Solutions (MMS) more detailed records and information that are not otherwise reported to OMC. For LeafLine Labs, we *were* able to verify that its medical cannabis was tested prior to sale, using the additional data. However, we were still unable to trace all of Minnesota Medical Solutions' product and verify that it was tested prior to its sale because of Minnesota Medical Solutions' data entry errors in its own tracking system, LeafLogix.[44]

Compliance with state reporting requirements and effective internal controls over the medical cannabis seed-to-sale process is important. In May 2017, OMC issued a revised administrative penalty order in the amount of $1,000 to Minnesota Medical Solutions for dispensing medical cannabis that had not passed potency testing at an MDH-approved independent laboratory prior to sale.[45] OMC made this finding as a result of an investigation initiated from a patient who reported they had used and experienced an adverse reaction from MMS's product.

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[42] *Minnesota Statutes* 2019, 152.29, subd. 4, requires that, for each patient, each manufacturer must report on a monthly basis (1) the amount and dosages of medical cannabis distributed; (2) the chemical composition of the medical cannabis; and (3) the tracking number assigned to any medical cannabis distributed. However, OMC staff told us that they directed each of the manufacturers to *exclude* patient identifiers and medical cannabis tracking numbers from their monthly reports to OMC.

[43] In particular, the data in the Medical Cannabis Registry (specifically, the tracking number and "lot ID") used by OMC are not reliable for tracking purposes. In many instances, the lot ID or the tracking number assigned to sold medical cannabis was missing or did not align with a manufacturer's own naming protocols.

[44] Minnesota Medical Solutions used one tracking number to monitor its own medical cannabis production and a different identifier for prescriptions recorded in the Medical Cannabis Registry. Within Minnesota Medical Solutions' own tracking system—LeafLogix—the assigned tracking number did not follow MMS's own naming protocols in 94 out of 665 instances, for a 14 percent exception rate.

[45] Michelle Larson, Director, Office of Medical Cannabis, Minnesota Department of Health, letter to Kyle Kingsley, Chief Executive Officer, Minnesota Medical Solutions, LLC (aka Vireo Health), May 30, 2017, Administrative Penalty Order.

RECOMMENDATIONS

The Minnesota Department of Health should improve its internal controls over the tracking and testing of medical cannabis. Specifically, the Minnesota Department of Health should:

- **Require accurate and complete reporting of tracking numbers for the cultivation, production, testing, and sale of any medical cannabis.**
- **Routinely review the Medical Cannabis Registry data for accuracy and completeness.**
- **Continue to work with Minnesota IT Services and the manufacturers to modernize the Medical Cannabis Registry system and reporting process to ensure more accurate seed-to-sale recordkeeping.**

Detect Diversion

As part of MDH's oversight of the medical cannabis manufacturers, OMC staff conduct unannounced inspections of their facilities to review their recordkeeping, inventory, and premises.[46] The department also may examine the manufacturers' business and financial affairs, practices, and conditions of the entities, and may enlist subject matter experts—such as experts in security controls—for this purpose.[47] MDH oversight helps ensure that the two approved manufacturers comply with legal requirements to provide a reliable and ongoing supply of medical cannabis and have controls to help prevent and detect diversion of the drug from the program.[48]

FINDING 7

The Minnesota Department of Health did not have adequate controls to help prevent and timely detect diversion or loss of medical cannabis by a manufacturer.

OMC did not require an independent examination of either manufacturer until March 2018, nearly three years after they began selling medical cannabis to patients. At that time, OMC contracted with a certified public accountant to examine Minnesota Medical Solutions' production operations, including inventory control measures, regulatory compliance, physical and data security, and other activities. At the time of our audit, OMC had yet to conduct an independent examination of LeafLine Labs.

Independent examinations can identify potential risks and help MDH inspectors target areas to monitor compliance with legal requirements. Had there been more rigorous oversight of manufacturers' compliance, OMC may have been able to detect a serious

[46] *Minnesota Statutes* 2019, 152.29, subd. 1(h).

[47] *Minnesota Statutes* 2019, 152.37, subd. 3.

[48] *Minnesota Rules*, 4770.1800, subp. 1, electronically published February 20, 2015.

compliance issue that occurred at Minnesota Medical Solutions. Specifically, OMC was notified in mid-2016 that two Minnesota Medical Solutions' officers had transported the product across state lines to New York in December 2015. These individuals subsequently left Minnesota Medical Solutions. In February 2017, a Wright County prosecutor charged the two MMS officers with intentionally transferring medical cannabis to a person other than allowed by law.[49] In September 2019, a Wright County judge approved an agreement that the Wright County Attorney's Office would dismiss the charges if each of the individuals completed one year of unsupervised probation and performed 80 hours of community service.[50]

In response to these events, OMC staff told us that they would have better, ongoing insight into the manufacturers' production and inventory if Minnesota's medical cannabis program utilized a single, state-centralized seed-to-sale track and trace inventory system. As we noted in the previous section, we observed deficiencies in the way medical cannabis products and testing are recorded and tracked for the program. A state-centralized system could provide more timely access to manufacturers' inventory records and other business information, enhance product recall capabilities, and help track the reasons that plants get removed from inventory.

OMC representatives also told us that they have recently expanded their oversight of the manufacturers in response to changes in state law.[51] The 2019 Legislature amended the state's Health Enforcement Consolidation Act—an initiative to promote compliance, deterrence, and effective enforcement—to include the medical cannabis program. The statutory change allows MDH wider discretion in the enforcement of legal requirements and use of administrative penalties for noncompliance.

RECOMMENDATION

The Minnesota Department of Health should conduct more frequent examinations of the medical cannabis manufacturers that include a review of their internal controls to prevent and detect diversion, theft, or loss of medical cannabis in a timely manner.

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[49] *State v. Bultman*, No. 86-CR-17-499 (10th Dist. Wright County, Feb. 6, 2017) (complaint); *State v. Owens*, No. 86-CR-17-500 (10th Dist. Wright County, Feb. 6, 2017) (complaint). The Wright County prosecutor charged Minnesota Medical Solutions' chief security officer and chief medical officer with intentionally transferring medical cannabis to a person other than allowed by law, in violation of *Minnesota Statutes* 2017, 152.33, subd. 1. According to the complaints, the defendants transferred 5.6 kilograms of concentrated cannabis oil from Minnesota Medical Solutions to Vireo Health, a Minnesota Medical Solutions-owned business located in New York.

[50] *Bultman*, No. 86-CR-17-499 (10th Dist. Wright County, Sept. 26, 2019) (unpublished order); *Owens*, No. 86-CR-17-500 (10th Dist. Wright County, Sept. 26, 2019) (unpublished order). As part of this case, the judge asked the Minnesota Court of Appeals to decide whether sister wholly owned subsidiaries of the same parent company are one "person," so that a transfer of cannabis oil from one subsidiary to the other cannot violate *Minnesota Statutes* 2017, 152.33, subd. 1. The appellate court ruled no. The panel held that sister wholly owned subsidiaries of the same parent corporation are separate "persons" under the plain language of *Minnesota Statutes* 2017, 152.33, subd. 1. *State v. Owens*, 930 N.W.2d 1, 7 (Minn. Ct. App. 2019), *review denied* (Aug. 6, 2019).

[51] See *Minnesota Statutes* 2019, 144.989- 144.993; and *Laws of Minnesota* 2019, First Special Session, chapter 9, art. 11, sec. 37, codified as *Minnesota Statutes* 2019, 144.99, subd. 1.


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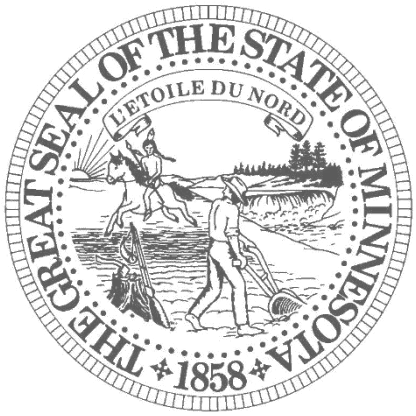
List of Recommendations

- The Minnesota Department of Health should verify that a health care practitioner's license is active and in good standing when the department approves a new patient for the medical cannabis program, as required by state statute. (p. 12)
- The Minnesota Department of Health should amend the Minnesota Department of Health's rules to require a health care practitioner to notify the department of a change in license status or when discontinuing care for patients in the program. (p. 12)
- The Minnesota Department of Health should comply with department policy and ensure that a parent or a legal guardian provides valid, original documents that establish the relationship with the patient. (p. 13)
- The Minnesota Department of Health should continue to work with Minnesota IT Services to improve the storage capacity of the Medical Cannabis Registry. (p. 13)
- The Minnesota Department of Health should comply with state statutes and collect the correct fees from patients in the medical cannabis program. (p. 16)
- The Legislature should consider whether disabled patients who receive Social Security retirement benefits should pay a reduced medical cannabis fee and amend state statutes accordingly. (p. 16)
- The Minnesota Department of Health should comply with state policy and perform monthly reconciliations and ensure separation of employee duties when registering patients and processing fee payments for the medical cannabis program. (p. 17)
- The Minnesota Department Health should comply with state statutes and ensure that each of the registered manufacturers maintains a contract with an independent laboratory for purposes of testing medical cannabis. (p. 20)
- The Minnesota Department of Health should improve its internal controls over the tracking and testing of medical cannabis. Specifically, the Minnesota Department of Health should:
  - Require accurate and complete reporting of tracking numbers for the cultivation, production, testing, and sale of any medical cannabis.
  - Routinely review the Medical Cannabis Registry data for accuracy and completeness.
  - Continue to work with Minnesota IT Services and the manufacturers to modernize the Medical Cannabis Registry system and reporting process to ensure more accurate seed-to-sale recordkeeping. (p. 22)
- The Minnesota Department of Health should conduct more frequent examinations of the medical cannabis manufacturers that include a review of their internal controls to prevent and detect diversion, theft, or loss of medical cannabis in a timely manner. (p. 23)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January 8, 2020

James Nobles
Office of the Legislative Auditor
140 Centennial Building
658 Cedar Street
St. Paul, MN 55155

Dear Mr. Nobles:

Thank you for the opportunity to review and comment on the findings and recommendations from the recent audit of the Office of Medical Cannabis for the time period July 2016 through December 2018. We appreciate and value the professional review conducted by the audit staff.

The department takes its responsibility to ensure adequate internal controls over the medical cannabis program seriously and has provided a detailed response to each finding below. While the purpose of the audit is to focus on specific finance-related legal requirements and internal controls and not to consider the overall structure or environment in which the program operates, it is important to offer a few points of context before responding to each finding.

The Office of Medical Cannabis (OMC) is a relatively new program. The law establishing this program was passed in the 2014 legislative session and the program served its first patients in 2015. When the OMC was first established, Minnesota was one of only a few states with legalized cannabis for medical purposes. While there are now 33 states where medical cannabis is legal, the regulation of medical cannabis in Minnesota and across the country is still in its early stages of development. Consequently, there have been very few established best practices to draw on.

At the same time, OMC is regulating an industry that continues to evolve rapidly and our program continues to expand. The report notes that each manufacturer is limited to one patient center in each of four regions. The 2019 legislature passed a law to double the number of patient centers permitted in the program. OMC anticipates new centers to begin serving patients in 2020.

Finally, the program by its very design presents regulatory challenges. For example, the law requires a vertically integrated system limited to two companies that each cultivate, process, and dispense medical cannabis. The current model puts the state at risk if we were to lose a manufacturer due to regulatory action or other factors. One manufacturer could not adequately serve the existing patient population. We must consider these challenges with each regulatory action we take.

The following statements describe the corrective actions already taken or that will be taken to address the findings and recommendations in your audit report.

Finding #1

The Minnesota Department of Health did not verify for all new patients that the license of a health care practitioner was active and in good standing.

Recommendation

The Minnesota Department of Health should verify that a health care practitioner's license is active and in good standing when the department approves a new patient for the medical cannabis program, as required by state statute.

Response

The department agrees with this finding but only partially agrees with the recommendation. MDH currently verifies practitioners are active and in good standing when the practitioner enrolls in our program. We also verify the practitioner is enrolled and was verified when a patient enrolls in our program. Verifying the practitioner more frequently than once per quarter would not improve controls substantially, since the Board of Medical Practice takes actions only once per quarter.

What the audit found is that one practitioner had retired and their license had become inactive after OMC's initial verification, and another practitioner had entered their license number incorrectly. To address the issue where a practitioner's status may change, OMC will, on a quarterly basis beginning April 2020, request a list of inactive doctors, physician's assistants, and Advanced Practice Registered Nurses (APRNs) from the Board of Medical Practice since the last request and query the Registry for matches. If a match is found, OMC staff will manually inactivate the health care practitioner in the system.

To address transcription issues, OMC will provide training to call center staff, by March 2020, to catch application discrepancies upon initial approval.

Person Responsible: Megan Thompson, Operations Supervisor

Recommendation

The Minnesota Department of Health should amend the Minnesota Department of Health's rules to require a health care practitioner to notify the department of a change in license status or when discontinuing care for patients in the program.

Response

The department agrees with this finding and recommendation and will amend the administrative rules to reflect this change by June 30, 2020.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis

Finding #2

The Minnesota Department of Health did not keep valid documentation of the eligibility of parents or legal guardians for the medical cannabis program.

Recommendation

The Minnesota Department of Health should comply with department policy and ensure that a parent or legal guardian provides valid, original documents that establish the relationship with the patient.

Response

The department agrees with this finding and recommendation, and is currently complying with our policy but lacks the controls within our registry system to maintain the documentation. The department currently requests and verifies documentation demonstrating the parent or legal guardian relationship to the patient during the initial review process. However, OMC staff has identified major technology limitations with our registry--it will only maintain two documents at a time and does not create an event log when documents are added. If the patient uploads a new document, the initial document is lost. MNIT staff have developed a solution to this deficiency and are prepared to deploy the change by March 30, 2020. OMC staff are reviewing the solution and to determine its workability.

Person Responsible: Megan Thompson, Operations Supervisor

Recommendation

The Minnesota Department of Health should continue to work with the Minnesota IT Services to improve the storage capacity to the Medical Cannabis Registry.

Response

The department agrees with this finding and recommendation. MNIT staff have developed a solution to this deficiency and are prepared to deploy the change by March 30, 2020. OMC staff are reviewing the solution to determine its workability.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis and Robert Maki, Chief Business Technology Officer

Finding #3

The Minnesota Department of Health charged some medical cannabis patients a lower registration fee than permitted in state statutes.

Recommendation

The Minnesota Department of Health should comply with state statutes and collect the correct fees from patients in the medical cannabis program.

Response

The department has interpreted statute differently than the Office of the Legislative Auditor. The department will work with the Governor and Legislature to clarify who is eligible for the reduced fee. OMC staff will implement any changes needed to comply with legislative intent. Until then, OMC will continue charging fees based on our interpretation—that disabled veterans receiving Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), and disabled seniors who had received Social Security Disability Insurance and have transitioned to Social Security retirement benefits are both eligible for the reduced fee. The department anticipates this issue to be resolved after the legislative session ends and can notify patients of changes, if needed with an estimated completion date of June 30, 2020.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis

Recommendation

The Legislature should consider whether disabled patients who receive Social Security Retirement benefits should pay a reduced medical cannabis fee and amend state statutes accordingly.

Response

The department agrees with this finding and recommendation and is ready to work with the legislature to address the issue in the 2020 legislative session.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis

Finding #4

The Minnesota Department of Health did not adequately reconcile some medical cannabis patient fees or ensure employee separation of duties when handling these payments.

Recommendation

The Minnesota Department of Health should comply with state policy and perform monthly reconciliations and ensure separation of employee duties when registering patients and processing fee payments for the medical cannabis program.

Response

The department agrees with this finding and recommendation. To conduct a full three-way financial reconciliation, our existing patient registry system would need to be modified in order to log and report non-electronic payments to allow department staff to see individual payment records. OMC staff will work with MNIT Services to determine if there is a way to modify our existing system, or if need be upgrade our registry to address this issue. OMC has been working with MNIT to identify solutions that will expand and enhance our ability to track the many aspects of our program documentation. If new functionality is needed, it could take several years to issue a Request for Proposal (RFP), and implement new software. In that scenario, the estimated completion date would be July 2022.

To accommodate the needed separation of duties, OMC took an interim step in May 2019 to lock the deposits workbook and limit access to two staff, neither of whom can approve patients in the registry. Given the size of the OMC staff (12, half of whom are call center staff), OMC will work with other MDH divisions to provide needed staff support to meet the MMB standards related to separation of duties. OMC should have the backup support staff identified and trained by July 1, 2020.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis and Robert Maki, Chief Business Technology Officer

Finding #5

The Minnesota Department of Health did not ensure that each of the two medical cannabis manufacturers had a formal contract with a testing laboratory.

Recommendation

The Minnesota Department of Health should comply with state statutes and ensure that each of the registered manufacturers maintains a contract with an independent laboratory for purposes of testing medical cannabis.

Response

The department agrees with this finding and recommendation and is currently in compliance. Each manufacturer currently holds a formal contract with a testing laboratory. Minnesota Medical Solutions executed a formal contract with a laboratory in July 2018, and LeafLine Labs executed a formal contract in May 2019. During each manufacturer renewal process, the department will confirm that each registered manufacturer continues to hold a valid contract with independent laboratories for purposes of testing medical cannabis. The December 2019 renewal process confirmed that both manufactures had contracts. The department considers this recommendation complete.

Person Responsible: Megan Thompson, Operations Supervisor

Finding #6

The Minnesota Department of Health did not have adequate controls to ensure manufacturers accurately tracked and tested medical cannabis prior to sale.

Recommendation

The Minnesota Department of Health should improve its internal controls over the tracking and testing of medical cannabis. Specifically, the Minnesota Department of Health should require accurate and complete reporting of tracking numbers for the cultivation, production, testing, and sale of any medical cannabis.

Response

The department agrees with this finding and recommendation. OMC's current controls to track the manufacturer's product are manual and paper-based. A state-centralized seed-to-sale system would significantly improve our controls. OMC would need additional resources to acquire and implement this IT solution.

In December 2019, as a temporary measure until seed-to-sale software can be acquired, the manufacturer registration agreements were renewed including a provision that each manufacturer provide read-only access to OMC of the manufacturer's seed-to-sale system to monitor for activity suspect of diversion, inversion or lack of inventory control. Having read-only access does have limitations, but is a step forward in tracking and monitoring cultivation, processing, testing, and sale of medical cannabis.

In a future legislative session, the department will seek funding and technology solutions to review and revise our internal controls and systems; including a state-centralized seed-to-sale system, which the program currently does not have.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis

Recommendation

The Minnesota Department of Health should routinely review the Medical Cannabis Registry data for accuracy and completeness.

Response

The department agrees with this finding and recommendation. The department currently receives the laboratory results in PDF format. As of August 2019, OMC has established a system to enter the reports into a centralized searchable spreadsheet, which will allow us to better manage and track the data. The department considers this recommendation completed.

Person Responsible: Megan Thompson, Operations Supervisor

Recommendation

The Minnesota Department of Health should continue to work with Minnesota IT Services and the manufacturers to modernize the Medical Cannabis Registry system and reporting process to ensure more accurate "seed-to-sale" recordkeeping.

Response

The department agrees with this finding and recommendation. The registry and a seed-to-sale system are two separate systems. The OMC currently does not have a seed-to-sale software, but believes a state-centralized seed-to-sale system would be the best solution. OMC would need additional resources to acquire and implement this IT solution.

OMC has worked closely with MNIT Services to begin evaluating either upgrades to our existing registry, or moving to an RFP process to seek a new registry system. The estimated timeline for RFP, implementation and data migration is 2.5 years, which means the earliest a new system would be available would be July 2022.

In order to address some of the data entry errors, MNIT Services in conjunction with OMC and the manufacturers has piloted a new interface that links the State of Minnesota registry directly to the manufacturers' Seed to Sale systems for some data entry points. This interface sends some real time patient disbursement information to the registry at the time of a successful transaction, eliminating delays/double entry and mistakes in the registry and ensuring that data in both systems are consistent. As of early December 2019, the new method had been successfully piloted at both manufacturers. Deployment of the change is anticipated first quarter of CY2020.

In a future legislative session, the department will seek funding and technology solutions to review and revise our internal controls and systems, including a state-centralized seed-to-sale system, which the program currently does not have.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis and Robert Maki, Chief Business Technology Officer

Finding #7

The Minnesota Department of Health did not have adequate controls to help prevent and timely detect diversion or loss of medical cannabis by a manufacturer.

Recommendation

The Minnesota Department of Health should conduct more frequent examinations of the medical cannabis manufacturers that include a review of their internal controls to prevent and detect diversion, theft, or loss of medical cannabis in a timely manner.

Response

The department partially agrees with this finding and recommendation. More frequent independent examinations are only one way to prevent and detect diversion and inversion. Independent examinations are incredibly time and budget intensive and at least one manufacturer has stated to us that any costs they incur in conducting independent examinations will be passed along to the patients.

An alternative to independent examinations is a state-centralized seed-to-sale system, which could provide real-time inventory data, chain of custody information, as well as proactive system alerts, without having to physically visit each cannabis patient center across the state with increased frequency, or having to engage budget intensive contractors to provide examination reports.

In a future legislative session, the department will seek funding either for independent examinations, to avoid the costs being added to the price of medication, or a state-centralized seed-to-sale system, which the program currently does not have.

Person Responsible: Chris Tholkes, Acting Director Office of Medical Cannabis

Sincerely,

Jan Malcolm
Commissioner of Health
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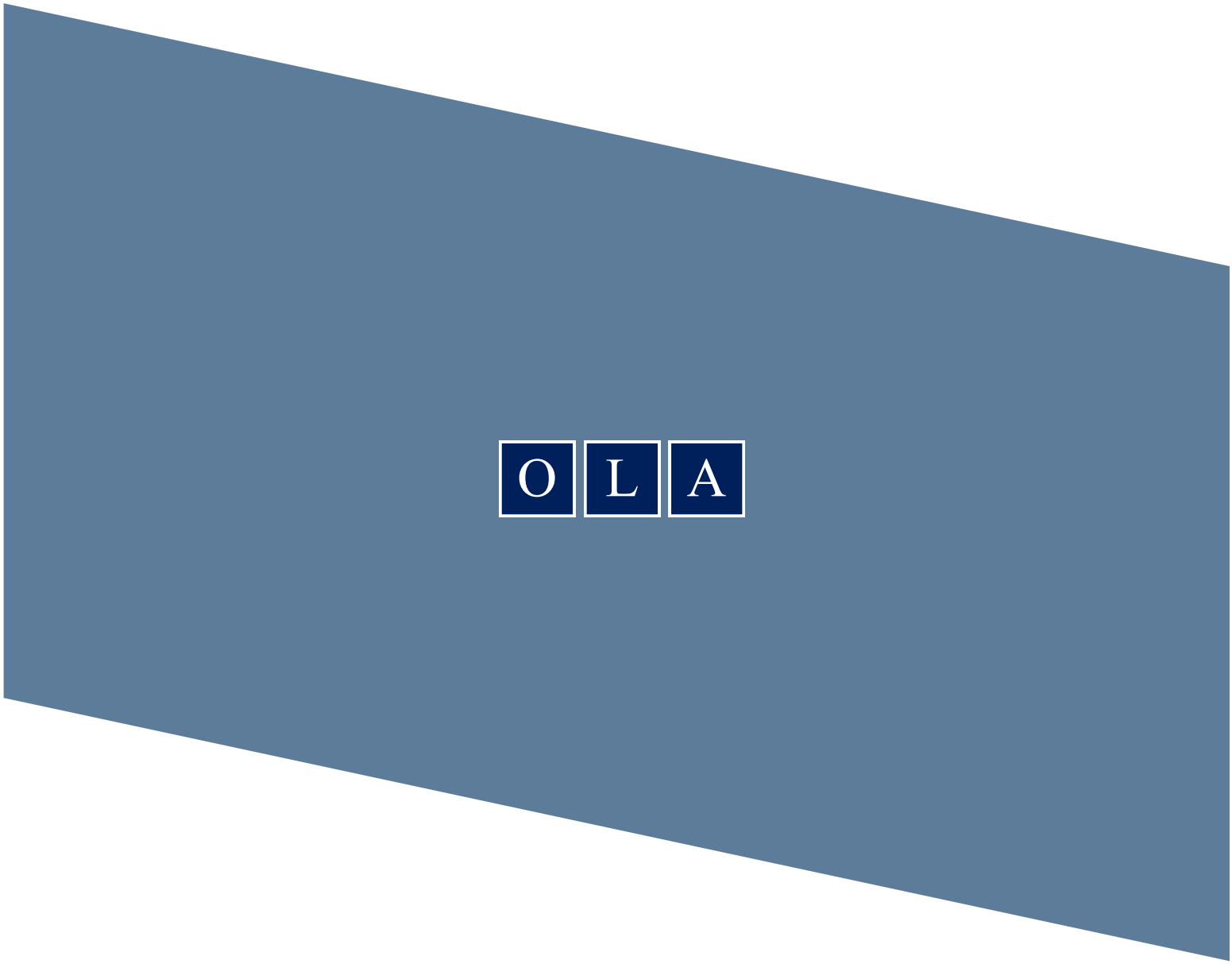

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