Legislative Audit Commission
Audit Subcommittee

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Minnesota Department of Health
Office of Medical Cannabis

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Why Audit?

New Program
Created in 2014

Increased Enrollment/Demand
Fiscal Year 2019
17,200 patients enrolled

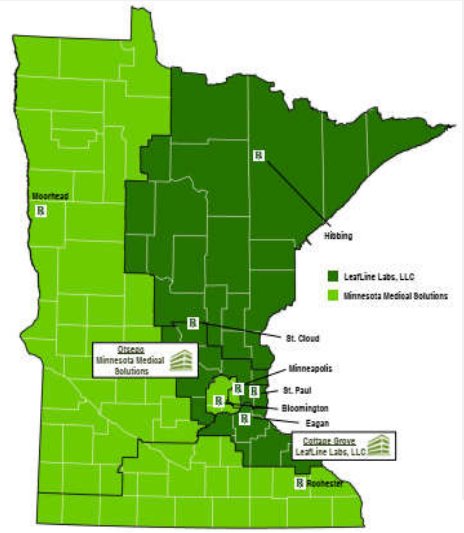
Background

- MDH Office of Medical Cannabis (OMC) oversees program and authorizes participants, manufacturers, laboratories
- Health care practitioners certify patients with a qualifying condition to have access to medical cannabis
- Two in-state manufacturers grow, produce, and dispense
- Laboratories test medical cannabis for content, contamination, and stability

Medical Cannabis Manufacturer Service Regions, July 2019

Each manufacturer:

- One manufacturing location
- Four regions
- Pharmacy dispensaries



Background

Medical Cannabis:

- Derived from 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.
- Allowed for limited health conditions (cancer, MS, other)

Audit Objectives and Scope

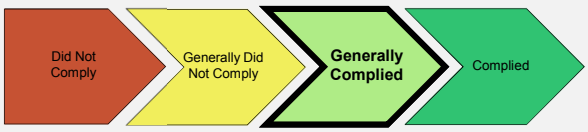
- MDH internal controls:
  - Authorize program participants
  - Process fee payments and financial transactions
  - Ensure compliance by manufacturers to track and test medical cannabis and prevent and timely detect diversion
- MDH compliance with significant legal requirements
- Audit period: July 1, 2018, through December 31, 2018

Conclusions

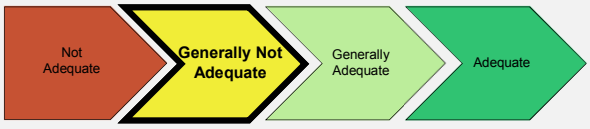
MDH generally complied with select legal requirements; some exceptions related to participant authorization, fee payments, and manufacturer contracts.

Internal controls over the areas in our audit scope were generally not adequate.

Legal Compliance



Internal Controls



Findings: Authorize Participants

- MDH did not verify for all new patients that the license of their health care practitioner was active and good standing.
- MDH did not keep valid documentation of the eligibility of parents or legal guardians for the medical cannabis program.
  - Registry system limitations
  - Weak documentation standards

Recommendations

MDH should:

- Verify a health care practitioner's license is active and in good standing for all new patients
- Amend MDH rules to require practitioners to notify MDH of change in license status or when discontinuing care
- Ensure that parent or legal guardian provides valid documents
- Improve storage capacity of the Medical Cannabis Registry

Findings: Collect and Safeguard Fees

- MDH charged some medical cannabis patients a lower registration fee than permitted in state statutes.
  - $200 fee; $50 if patient receives Social Security disability or Supplemental Security Insurance payments or enrolled in medical assistance or MinnesotaCare
- MDH did not adequately reconcile some medical cannabis patient fees or ensure employee separation of duties when handling payments.

Recommendations

MDH should:

- Collect correct fees from patients
- Perform monthly reconciliations and ensure separation of employee duties when registering patients and processing payments

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.

Findings: Track and Test Medical Cannabis

- MDH did not ensure that each of the two medical cannabis manufacturers had a formal contract with a testing laboratory.
- MDH did not have adequate controls to ensure manufacturers accurately tracked and tested medical cannabis prior to sale.
  - Program relies on multiple information systems
  - No single unique identifier from cultivation to testing and sale
  - OMC does not collect complete inventory data
  - Data entry errors and omissions in the Medical Cannabis Registry

Finding: Detect Diversion

- MDH did not have adequate controls to help prevent and timely detect diversion or loss of medical cannabis by a manufacturer.
  - Unannounced inspections in recent years
  - No independent examinations until March 2018
    - One manufacturer with serious compliance issue

Recommendations

MDH should:

- Ensure that each manufacturer maintains a contract with a laboratory to test medical cannabis.
- Improve controls over tracking and testing medical cannabis.
  - Require accurate and complete reporting of tracking numbers
  - Routinely review Medical Cannabis Registry data
  - Work with MNIT Services and manufacturers to modernize the Medical Cannabis Registry and reporting process
- Conduct more frequent examinations of manufacturers.

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Questions?

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Regenerative Medicine Minnesota

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Background

Purpose: Bring Minnesota to forefront of regenerative medicine

Structure:

- Collaborative partnership between University of Minnesota and Mayo Clinic
- Five member oversight board
  - Two co-chairs
    - Dean of University of Minnesota Medical School
    - Director of Mayo Clinic Center for Regenerative Medicine
  - Two board members not affiliated with University of Minnesota and Mayo Clinic

Funding:

- Began in Fiscal Year 2015
- Used primarily for grants but not used for administrative or monitoring expenses

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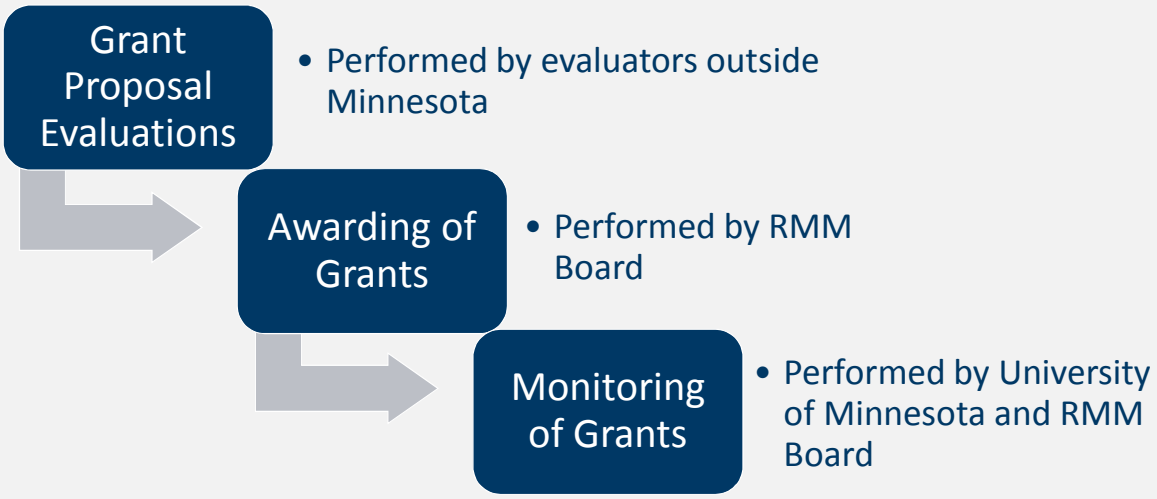
Grant Process



Why Audit?

Complaint

Allegation of mismanagement

Additionally, our office has not audited Regenerative Medicine Minnesota

Objectives

Grant Proposal Evaluation and Awarding

Did Regenerative Medicine Minnesota **develop adequate controls** to objectively evaluate proposals and award grants?

Did Regenerative Medicine Minnesota **evaluate proposals** against its established criteria and **fund the top scoring projects**?

Objectives

Grant Award Oversight

Did Regenerative Medicine Minnesota **develop adequate controls** to ensure that funded projects met deliverables and expected outcomes?

Did Regenerative Medicine Minnesota partnership only reimburse **allowable project costs**?

Regenerative Medicine Minnesota Grant Activity

	Fiscal Year			
	2015	2016	2017	2018
Grants Awarded	**$4,421**	**$3,746**	**$4,469**	**$4,801**
Grant Expenditures by Category				
Research	$2,963	$ 2,259	$2,190	$1,175
Biobusiness Development	695	446	881	328
Education	700	714	482	226
Clinical Care	3	0	0	0
Total Expenditures	**$4,361**	**$ 3,419**	**$3,553**	**$1,729**

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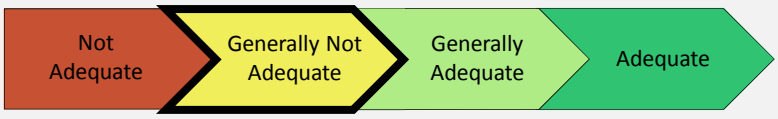
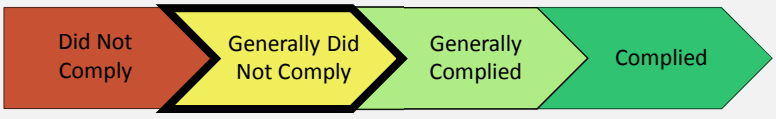
Conclusions

Internal Controls



Legal Compliance



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Finding 1: State Appropriation Law

Regenerative Medicine Minnesota spent some of its state appropriation on grants the law did not authorize

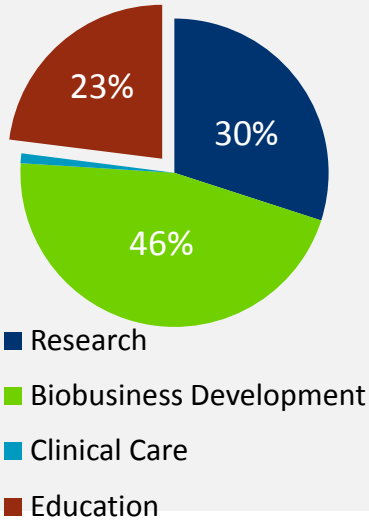
State Appropriation Law

- Regenerative medicine research
- Clinical translation
- Commercialization

Regenerative Medicine Minnesota

- Research
- Education
- Biobusiness development
- Clinical care

Grants in Question



Breakdown of Education Grants

K-12 Education Grants
- 52% of all education grants
- $441,000

All Other Education Grants
- 48% of all education grants
- $2,019,000

Recommendation

Regenerative Medicine Minnesota partners should not let evaluators score proposals if they have an affiliation with other competing projects.

Finding 3: Proposal Evaluation

Grant proposals did not always receive the same level of scrutiny

- For example, in Fiscal Year 2018, discovery science research awards went to proposals that received only two evaluations
  - 32% received two evaluations
  - 68% received three evaluations

Recommendation

Regenerative Medicine Minnesota partners should ensure that all grant proposals receive a consistent review.

Finding 4: Scoring Errors

Due to calculation errors, two proposals erroneously received awards for $250,000 when competing proposals received higher scores

- Additional errors noted in testing:
  - Incomplete evaluations
  - Scores not following guidelines
  - Transferring errors
  - Additional calculation errors

Recommendation

Regenerative Medicine Minnesota partners should conduct a comprehensive review of the process used to compile grant proposal scores for decision making.

Finding 5: Inconsistent Grant Terms

Grant contracts for Mayo Clinic awards differed from those of other institutions

- Mayo Clinic contracts were less restrictive
  - Ability to charge costs to grants up to 90 days before award begins
  - Ability to make changes to approved grant budget categories (budget or scope cannot change)

Recommendation

Regenerative Medicine Minnesota partners should standardize terms in grant contracts.

Finding 6: External Grant Reimbursements

- External grant reimbursement requests lack sufficient documentation to determine whether costs are allowable
- One external grant reimbursement included $6,454 of costs incurred before the start of the award period

Recommendations

Regenerative Medicine Minnesota partners should outline documentation requirements that will support the ability to validate the allowability of costs.

Regenerative Medicine Minnesota partners should seek recovery of the $6,454 in costs that were inappropriately paid to one grantee.

Finding 7: Report Review

Board members do not consistently review interim and final progress reports

- Only 37% of interim reports were reviewed by the board
- Only the University board co-chair reviews all final reports

Recommendation

The Regenerative Medicine Minnesota Board should review all interim and final progress reports.

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Questions?

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