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Executive Office of Health and Human Services
Department of Public Health
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April 8, 2016

Steven T. James
House Clerk
State House Room 145
Boston, MA 02133

William F. Welch
Senate Clerk
State House Room 335
Boston, MA 02133

Dear Mr. Clerk,

Pursuant to Section 2K K K K of Chapter 29 of the General Laws, please find enclosed a report from the Department of Public Health entitled "*Medical Marijuana Trust Fund Annual Report.*"

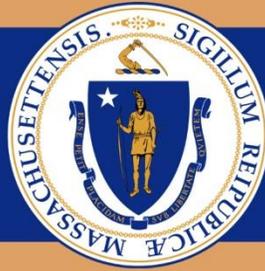
Sincerely,

Monica Bharel, MD, MPH
Commissioner
Department of Public Health

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Charles D. Baker
Governor

Karyn Polito
Lieutenant Governor



Marylou Sudders
Secretary

Monica Bharel, MD, MPH
Commissioner

Medical Marijuana Trust Fund Annual Report

April 2016



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Legislative Mandate

The following report is hereby issued pursuant to Section 2KKKK of Chapter 29 of the General Laws, which reads as follows:

Section 2KKKK. There shall be established and set upon the books of the commonwealth a separate fund to be known as the Medical Marijuana Trust Fund, to be expended without prior appropriation by the department of public health. Unless a greater amount is authorized by law, the fund shall consist of revenue generated from fees collected after July 1, 2013, as authorized by section 3B of chapter 7 of the General Laws and section 13 of chapter 369 of the acts of 2012. The commissioner of public health or a designee shall administer the fund and shall make expenditures from the fund for the administrative costs of operations and programs related to said chapter 369. The department may incur expenses and the comptroller may certify for payment, amounts in anticipation of expected receipts; provided, however, that no expenditure shall be made from the fund which shall cause the fund to be in deficit at the close of a fiscal year. Moneys deposited in the fund that are unexpended at the end of a fiscal year shall not revert to the General Fund. The commissioner shall report annually not later than March 1 to the house and senate committees on ways and means on the fund. The report shall include, but not be limited to, revenue received by the fund, revenue and expenditure projections for the forthcoming fiscal year and details of all expenditures from the fund, including an analysis of whether the fund expenditures assisted the department in meeting its regulatory mandates.

Executive Summary

Purpose

The purpose of this report is to provide information regarding the Medical Marijuana Trust Fund, Section KKKK of Chapter 29 of the General Laws, revenues and expenditures, and an analysis of whether these expenditures assisted the Department of Public Health (DPH) in meeting its regulatory mandates.

Findings

An analysis of revenues and expenditures for the Medical Marijuana Trust Fund for Fiscal Years 2014, 2015, and 2016 (projected) demonstrates that expenditures assisted DPH in meeting its regulatory mandates.

Recommendations

Revenues and expenditures from the Medical Marijuana Trust fund will continue to support the operations of DPH to further the operations and programs related to the Humanitarian Medical Use of Marijuana Act, Chapter 369 of the Acts of 2012.

Introduction

On November 6, 2012, Ballot Question 3, "An Initiative Petition for a Law for Humanitarian Medical Use of Marijuana" passed with 63.3% of the vote, making Massachusetts the 18th state in the nation, in addition to the District of Columbia, to approve the use of marijuana for medical purposes. The resulting law, Chapter 369 of the Acts of 2012, "An Act for the Humanitarian Medical Use of Marijuana,"(Act) required DPH to issue regulations, 105 CMR 725.000, et seq., implementing the ballot measure, including the registration of non-profit organizations to cultivate and dispense marijuana for medical use, and the registration of physicians, patients, personal caregivers, and dispensary agents.

DPH also established the Medical Use of Marijuana Program (Program), which is required by the ballot question to be revenue neutral, with all fees collected used for day-to-day operations that include compliance, stakeholder support services, Registered Marijuana Dispensary (RMD) application processing, and related information technology support systems.

In the three years following passage of the ballot measure, DPH developed one of the first dispensary-based programs in the country grounded in the core principles of patient access and public safety. In December, 2014, the first RMD obtained a Final Certificate of Registration, beginning retail sales of marijuana for medical use in Salem in June, 2015. Three other RMDs in Brockton, Northampton, and Ayer opened for retail sales later in 2015. Two additional RMDs commenced sales in early 2016, one in Brookline and one in Lowell. Twelve other RMDs with provisional certificates of registration are in the inspections phase at various stages of build-out. Over 98% of the state's population will be within 25 miles of an RMD based upon actual and proposed locations. As of January 31, 2016, 36,249 ounces of marijuana for medical use had been sold in the form of flower product, marijuana-infused products (MIPs) or oils.

The Program has implemented a dedicated Support Center (Center) to provide constituents with Program and regulatory information, and process applications for registration from patients, caregivers, and RMD Agents. The Center's dedicated team of five full-time employees field an average of 225 calls, in addition to emails, each day from constituents inquiring about topics such as the online registration system, RMD locations, patient or personal caregiver questions, and regulatory issues.

The Center reviews approximately 100 electronic and paper applications for registration for patients, personal caregivers or physicians each day. As of January 31, 2016, 132 physicians were registered and had certified 24,581 patients to possess marijuana for medical use. By that date, 19,279 patients were registered with the Program and had received registration cards, along with 1,064 caregivers and 320 RMD agents.

On June 29, 2015, the Program launched revised procedures for processing new RMD applications for Certificates of Registration based upon a market-driven licensure model. The Program created guidance documents regarding non-profit compliance requirements and

background investigations to provide greater transparency in its review. Applications are reviewed for compliance with the Act, the Regulations and the guidance documents, and applicants are provided feedback and an opportunity to revise their applications to bring them into compliance. Rather than fixed deadlines, applications are accepted on a rolling basis. The majority of application materials are now posted on the Program's website to allow the public to review information about the pending applications, as well as the status of each application. As of January 31, 2016, 159 applications had been received as part of the revised process and are in various stages of review. One provisional certificate of registration has been issued.

On November 19, 2015, in order to take advantage of new scientific literature and feedback from testing laboratories, RMDs, patient advocates and other stakeholders, the Program's compliance unit released proposed revised protocols that detail requirements associated with testing marijuana for medical use. The protocols are now based upon the United States Pharmacopoeia (USP) standards for drugs and nutritional supplements that are developed and constantly revised by scientists from industry, academia and government. The protocols were posted for public comment immediately following their release, and following the submission of 185 public comments, which were reviewed in consultation with the DPH Bureau of Environmental Health, additional revisions were made. The final protocols are anticipated to go into effect in the Spring of 2016.

In 2016, significant enhancements are planned for Medical Use of Marijuana Online System (MMJ Online System), the public-facing website utilized by patients, caregivers, physicians and RMDs for patient certification and registration. Enhancements will focus on a simplified interface to improve overall user satisfaction, more robust data reporting capabilities, and enhanced functionality to support activities associated with RMDs such as inspections and related follow-up. In addition, the monthly dashboard made available to the public, relaying key data such as patients certified and product sold, will be improved to include a more comprehensive data set. Finally, the Program will continue to grow and adapt as this new industry evolves in Massachusetts.

Report Body

As required by the Act, the Program must remain revenue neutral with all fees collected to be used for day-to-day operations that include three major programmatic functions: (1) A dedicated support center fielding calls and conducting processing activities for the ongoing review and approval of patient, caregiver and RMD registration applications; (2) A compliance unit responsible for the ongoing review of RMDs and their associated on-site inspections; and (3) Activities associated with the review, processing and posting of new RMD applications for Certificates of Registration.

Fees include patient, RMD and RMD agent registration and renewals, hardship cultivation registration and renewal, registration card replacement, and RMD activities such as architectural reviews, name changes, and changes of location. Addendum 1 outlines the Program's fee schedule.

A. Fiscal Year 2014

1. Program Highlights

Revenues supported key Program objectives in FY2014, including retaining expert consultants and operations support services to assist with the application review process and launch of the Program, IT development expenses to build the MMJ Online System, phased-in hiring of staff to support daily operations, and the improvement of Program work space.

2. Revenues

The Program collected a total of \$3,821,700 in revenue. \$3,000,000 in funds were received from RMD phase 2 applications, the largest source of revenue for the year. Additional revenue included \$550,167 in RMD registration and name change fees and \$271,500 in RMD phase 1 application fees. Addendum 2 details revenues for FY2014.

3. Expenses

FY2014 expenses totaled \$3,426,893 and included \$14,796 in administrative costs such as office supplies and printing expenses, \$1,397,528 in information technology development costs associated with the MMJ Online System, and \$123,100 in infrastructure costs that included the printing of registration cards and the processing of credit card payments by patients and RMD Agents for Program registration. Operational services provided to the Program by information technology and other expert consultants totaled \$1,587,886. Salaries and benefits totaled \$303,034, and employee related expenses for travel and reimbursements totaled \$549.

As moneys deposited in the fund that are unexpended at the end of a fiscal year shall not revert to the General Fund, a positive balance of \$394,807 rolled over into FY2015. Addendum 2 details expenses for FY2014.

B. Fiscal Year 2015

1. Program Highlights

Revenues received supported a number of key milestones in FY2015 including the launch of the MMJ Online System, the opening of four RMDs, an overhaul of the review process for new RMD applications, and the continued expansion of Program staff to support operational activities. Beginning May 15, 2015, the Program was transferred to the Bureau of Healthcare Safety and Quality (BHCSQ) given its similar mission to regulate and establish standards for the accreditation of health care providers and facilities.

2. Revenues

Revenues totaled \$1,663,134 and included a \$394,807 balance forwarded into the trust account from FY2014. RMD fees totaled \$977,197 and included RMD registrations, RMD Agent registrations and other RMD fees. Phase 1 new RMD application fees totaled \$120,000. Patient registration fees totaled \$171,130.

The Program experienced a revenue shortfall in FY2015 due to total revenues falling below projections, a lack of funding for significant start-up costs associated with launching the Program, and information technology costs exceeding original projections. To address this shortfall, \$659,768 in payroll expenditures was transferred to the BHCSQ state appropriation. Addendum 3 details FY2015 revenues.

3. Expenses

Expenses included \$10,200 in administrative costs such as office supplies and printing expenses, \$860,832 in information technology maintenance and development costs associated with the MMJ Online System, and \$224,455 in infrastructure costs that included the printing of registration cards and the processing of credit card payments by patients and RMD Agents for Program registration. Operations services provided to the Program by information technology and other expert consultants totaled \$452,912. Salaries and benefits totaled \$104,670 (per above, an additional \$659,768 in payroll expenses was transferred to BHCSQ). Finally, employee related expenses for travel and reimbursements totaled \$4,061. Addendum 3 details FY2015 expenditures totaling \$1,657,130.

C. Fiscal Year 2016 (Projected)

1. Program Highlights

In the first half of Fiscal Year 2016, revenues received supported continued expansion of the Program. As of January 31, 2016, 159 new applications were received by the Program as part of the new RMD application process that launched in June 2015; new proposed marijuana for medical use product testing Protocols were released for public comment and posted on the

Program's website in November 2015; the sixth RMD to receive a Final Certificate of Registration opened its doors to patients; and eleven RMDs continue to develop at various stages of build-out.

2. Revenues (Projected)

A total of \$3,301,004 in revenue is budgeted, including a \$6,004 balance forwarded into the trust account from FY2015 due to a combination of higher revenues of \$4,533 and lower expenditures of \$1,470 related to prompt pay discounts. The highest revenue stream includes \$1,200,000 from Phase 2 application fees for new RMD applicants, followed by \$1,000,000 in patient registration and renewal fees. \$915,000 in RMD and RMD Agent registration and renewal fees is expected. FY2016 projected revenues are outlined in Addendum 4. A \$320,610 surplus is projected to be forwarded into the FY2017 budget.

3. Expenses (Projected)

Expected expenditures include \$1,350,000 for information technology development costs associated with a major rollout of new enhancements for the MMJ Online System; \$1,242,649 in salaries and expenses, which is expected and reflects the addition of five new staff members for a total of 13. \$137,200, \$108,110 and \$102,400 have been allocated to infrastructure, administrative and operational services costs, respectively, and \$40,035 in employee-related fees, including training and reimbursements, is budgeted. FY2016 projected expenses are outlined in Addendum 4.

Conclusion

This report has highlighted key milestones and operational activities associated with the Medical Use of Marijuana Program, and provided information regarding revenues and expenses associated with the Medical Marijuana Trust Fund for Fiscal Years 2014, 2015, and 2016 (projected). An analysis of this information demonstrates that fund expenditures have assisted the department in meeting its regulatory mandates to register non-profit organizations to cultivate and dispense marijuana for medical use, and to register physicians, patients, personal caregivers, and dispensary agents. As of January 31, 2016, 19,279 patients were certified by a physician and active with the Program along with 1,064 caregivers and RMD Agents. Six RMDs are now dispensing marijuana for medical use in the form of flower, MIPs, and oils.

Addendum 1: Medical Marijuana Trust Fund Fee Schedule

- Patient registration: \$50, annually
- ID Card replacement: \$10
- Hardship cultivation: \$100
- Dispensary Agent registration: 500, annually
- Phase 1 Application: \$1,500
- Phase 2 Application: \$30,000
- RMD registration: \$50,000, annually
- Location change: \$10,000
- Name change: \$100
- Architectural review: \$8.25 per \$1,000 of construction costs
(\$1,500 minimum)

Addendum 2: Medical Marijuana Trust Fund - Revenues & Expenses - FY2014

Revenue:

RMD fees	\$	550,200
RMD application fees - Phase 1	\$	271,500
RMD application fees - Phase 2	\$	3,000,000
Total Revenues	\$	3,821,700

Expenditures:

Administrative	\$	14,796
Information technology	\$	1,397,528
Infrastructure	\$	123,100
Operational services	\$	1,587,886
Salaries and benefits	\$	303,034
Employee related expenses	\$	549
Total Expenditures	\$	3,426,893

Balance	\$	394,807
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Addendum 3: Medical Marijuana Trust Fund - Revenues & Expenses - FY2015

Balance forward from FY2014	\$	394,807
Revenue:		
RMD fees	\$	977,197
Patient fees	\$	171,130
RMD application fees - Phase 1	\$	120,000
RMD application fees - Phase 2	\$	-
Total Revenues	\$	1,268,327
Total Available for Expenditure in FY15	\$	1,663,134
Expenditures:		
Administrative	\$	10,200
Information technology	\$	860,832
Infrastructure	\$	224,455
Operational services	\$	452,912
Salaries and benefits	\$	764,438
Employee related expenses	\$	4,061
Total Expenditures	\$	2,316,898
Transfer to BHCSQ State Appropriation¹	\$	659,768
Total Expenditures Net Transfer	\$	1,657,130
Balance²	\$	6,004

¹ At the end of FY2015, \$659,768 in payroll expenditures was transferred to the BHCSQ state appropriation as the Program Trust Fund must remain revenue neutral per G.L. c.29 §2KKKK.

² A \$6,004 balance from FY2015 was forwarded into the FY2016 account due to a combination of higher revenues and lower expenditures related to prompt pay discounts that occurred following the close of FY2015.

**Addendum 4: Medical Marijuana Trust Fund - Revenues & Expenses - FY2016
(Projected)**

Balance forward from FY2016:	\$	6,004
Revenue:		
RMD fees	\$	915,000
Patient fees	\$	1,000,000
RMD application fees - Phase 1	\$	180,000
RMD application fees - Phase 2	\$	1,200,000
Total Revenues	\$	3,295,000
Total Available for Expenditure in FY15	\$	3,301,004
Expenditures:		
Administrative	\$	108,110
Information technology	\$	1,350,000
Infrastructure	\$	137,200
Operational services	\$	102,400
Salaries and benefits	\$	1,242,649
Employee related expenses	\$	40,035
Total Expenditures	\$	2,980,394
Balance	\$	320,610