### February 2014





Mary E. O'Dowd, MPH Commissioner

This document reports the status of the New Jersey Department of Health (Department), Medicinal Marijuana Program's (MMP) progress in implementing the New Jersey Compassionate Use Medical Marijuana Act (the Act). N.J.S.A. 26:61-1 et seq. This report provides an overview of the status of the Alternative Treatment Centers; describes the development and implementation of the patient, caregiver, and physician registries; discusses communication and education efforts; explains the testing protocols and regulatory process; reviews MMP's collaboration with external agencies and entities; and concludes with calendar year 2013 statistics.

#### **Alternative Treatment Centers (ATCs)**

Greenleaf Compassion Center (GCC) in Montclair, Essex County, was issued a permit to cultivate on April 16, 2012, and issued a final permit on October 15, 2012. GCC began dispensing medicinal marijuana to patients on December 6, 2012. As of December 31, 2013, 128 patients have been served, 651 transactions completed, and 22 pounds of product dispensed. The Department has 24/7 video surveillance of the ATC operation and read-only access to its inventory management system.

Compassionate Care Foundation (CCF) in Egg Harbor, Atlantic County, was issued a permit to cultivate on June 6, 2013, and issued a final permit on October 3, 2013. CCF began dispensing medicinal marijuana to patients on October 28, 2013. As of December 31, 2013, 360 patients have been served, 465 transactions completed, and 19 pounds of product dispensed. The Department has 24/7 video surveillance of the ATC operation and read-only access to its inventory management system.

Compassionate Care Center of America Foundation (CCCoA) in Woodbridge, Middlesex County, was issued a permit to cultivate on August 7, 2013, and issued a final permit on November 20, 2013. CCCoA is conducting business as Garden State Dispensary (GSD). GSD began dispensing medicinal marijuana to patients on November 22, 2013. As of December 31, 2013, 460 patients have been served, 718 transactions completed, and 29 pounds of product dispensed. The Department has 24/7 video surveillance of the ATC operation and read-only access to its inventory management system.

<u>Breakwater ATC</u> (Breakwater) has secured a host community in Middlesex County. (The host community has not been announced.) Examination of its principals and business structure was completed on December 13, 2013. Breakwater has initiated the buildout of its cultivation and dispensary facility.

<u>Compassionate Science ATC</u> (CSATC) has secured a host community in Bellmawr, Camden County. The examination of its principals, corporate structure and funding source was initiated on February 12, 2013, and is ongoing.

<u>Foundation Harmony</u> (Harmony) has secured a host community in Hudson County. (The host community has not been announced). Harmony has made an initial submission of examination documents of its principals, corporate structure and funding source.

#### **ATC Examinations**

The Department executed a Memorandum of Agreement with the Department of Law and Public Safety (LPS) on January 12, 2012. LPS agreed to assist the Department with obtaining credible and relevant criminal, financial, and other information, as well as provide expertise in the examination of the ATCs' principals and business structure to aid the Department in making informed decisions regarding the permitting of ATC entities as required under the Act and its regulations.

<u>Greenleaf Compassion Center</u> – Examination of GCC's principals and business structure was initiated on December 15, 2011. Examination was completed on April 16, 2012. The final report reflected the examination of one business structure and 12 principals. MMP issued the ATC permit upon review of the examination.

Compassionate Care Foundation – Examination of CCF's principals was initiated on February 13, 2012. Examination was completed on March 18, 2013. The examination reviewed three business structures and 22 principals. On December 26, 2012, CCF submitted an amended application that superseded the initial submission on February 13, 2012. The amended application contained two new business structures and excluded several principals previously examined. MMP issued the ATC permit upon review of the examination.

<u>Compassionate Care Center of America Foundation</u> – Examination of CCCoA was initiated on September 4, 2012. Examination was completed on April 24, 2013. The final report reflected the examination of three business structures and three principals. MMP issued the ATC permit upon review of the examination.

<u>Breakwater ATC</u> – Examination of Breakwater principals was initiated on August 24, 2012. Examination was completed on December 13, 2013. The final report reflected the examination of four business structures, 12 principals and six contractual agreements. Breakwater has initiated the buildout of its dispensary

and cultivation facility. The MMP is assisting them in attaining regulatory compliance.

<u>Compassionate Science ATC</u> – The examination of CSATC principals, corporate structure, and funding source was initiated on February 12, 2013, and is ongoing.

<u>Foundation Harmony</u> – Harmony has made an initial submission of examination documents of its principals, corporate structure, and funding source.

Examination timeframes are impacted by a number of factors including the complexity of the ATC business structure, their contractual agreements and their responsiveness to requests for information.

#### Patients/Caregiver Registry

The MMP developed an electronic patient and caregiver registration and payment process (the registry). The registration and payment process is an encrypted web application that provides security of personal, medical and financial information of the applicant. This registry opened on August 9, 2012. As of December 31, 2013, 1,670 qualifying patients and 197 caregivers are registered with the program. The MMP has issued identification cards to all 1,867 qualifying applicants completing the registration process. Additionally, all authorized debilitating illnesses are represented in the present patient population.

The patient and caregiver registration fee is \$200 and is valid for two years. Patients and caregivers that receive New Jersey Medicaid, current food stamp benefits, New Jersey Temporary Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits receive a reduced registration fee of \$20. Approximately 47% of registered patients and caregivers qualified for and received the reduced application fee of \$20.

The registration fee will be pro-rated for any patient who paid an initial registration fee but did not receive medicinal marijuana for a period of time. The prorated fee will be applied at the time of re-registration and will be calculated for the time period a patient did not have access to an ATC.

#### Physician Registry

The MMP developed an electronic physician registration process. There is no fee assessed for physician registration. The registration process is an encrypted web application that provides security of physician information.

Internal to this process is a daily validation of physician licensure status with the New Jersey Board of Medical Examiners. As of December 31, 2013, 250 physicians are registered as active with the program. All physicians registered with the program are listed on the MMP website. Patients may ask their primary physician to register with the MMP or they may locate a participating physician on the website by county and/or medical specialty.

Physicians who wish to participate in the program must hold an active New Jersey Medical license in good standing issued by the NJ Board of Medical Examiners, possess an active controlled dangerous substances registration issued by the NJ Division of Consumer Affairs that is not subject to limitation, and practice within the State of New Jersey.

Physicians must also establish a bona fide relationship with a patient in order to register them with the program. A bona fide physician-patient relationship means a relationship in which the physician has ongoing responsibility for the assessment, care, and treatment of a patient's debilitating medical condition whereby:

- The physician-patient relationship has existed for at least one year; or
- The physician has seen and/or assessed the patient for the debilitating medical condition on at least four visits; or
- The physician assumes responsibility for providing management and care
  of the patient's debilitating medical condition after conducting a
  comprehensive medical history and physical examination, including a
  personal review of the patient's medical record maintained by other
  treating physicians reflecting the patient's reaction and response to
  conventional medical therapies.

#### **Outreach & Communication**

As previously noted, the MMP developed a website that contains general information for the public as well as specific information for patients, caregivers, physicians, and ATCs. Within the website are links to scholarly articles and research to assist physicians on the palliative use of medicinal marijuana. The MMP has also created a webinar intended to provide physicians with an introduction to the program and guide them through the registration process.

The MMP developed a Customer Service Unit (CSU) for patients, physicians, ATCs, and the public. The CSU has responded to more than 16,650 public inquiries via telephone and e-mail. The CSU has also taken a hands-on approach with patients and caregivers to help assist them through the registration process.

The MMP also communicates with ATCs in the examination process to facilitate the review of submissions. Additionally, the MMP communicates daily with operational ATCs to monitor activity, obtain status reports, and resolve any programmatic issues to ensure compliance with the Act and applicable regulations.

#### **Education**

The MMP has partnered with the New Jersey Board of Medical Examiners, the Medical Society of New Jersey, and the Drug Policy Alliance to provide informational webinars and an electronic library of scholarly articles and research materials, which are available on the MMP website. The MMP web page has a physician resources section, which includes a webinar to introduce physicians to the program and to provide a guide through the registration process. The MMP, in collaboration with LPS, developed law enforcement guidelines and an identification card validation process.

#### Marijuana Testing Protocols

The MMP worked with several State agencies to develop marijuana sampling and testing protocols that ensure compliance with labeling standards and the quality of the product. Furthermore, the Department's Public Health Environmental Laboratory (PHEL) established additional scientific protocols for product sampling and testing.

The PHEL worked with the Department of Agriculture to develop protocols related to testing for molds and pesticides. The MMP sampling and testing process was developed after researching marijuana testing protocols in the United States, Canada, and Europe. Product testing is necessary to establish cannabinoid profiles and screen the product for mold and other contaminants that can be dangerous for patients with compromised immune systems.

#### **Regulatory Process**

The Department and LPS established a permitting process to thoroughly vet the financial and personal backgrounds of the principals associated with the ATCs. The permitting process is modeled after protocols and procedures for reviewing the background and finances of casino operators undertaken by the Division of Gaming Enforcement, within LPS. Additionally, the MMP has developed an:

- online registration process for patients, caregivers, and ATC employees.
   Successful applicants are issued an identification card specific to their role within the program;
- Identification Card system with various security features that mitigate counterfeiting and which can be validated by law enforcement through an online search; and
- ATC Monitoring Unit that conducts on-site inspections, monitors the ATCs by video in real time, and remotely accesses the ATC inventory management systems.

#### <u>Partnerships</u>

The Department has established partnerships with several State and private entities to implement the Act. LPS (Office of the Attorney General, New Jersey State Police, Board of Medical Examiners and Division of Gaming Enforcement), the departments of Agriculture, Environmental Protection and Treasury, the Motor Vehicle Commission, the University of Mississippi, the Drug Policy Alliance, and the Medical Society of New Jersey have all lent expertise to program implementation and operation.

#### **Calendar Year 2013 Statistics**

#### **Patient Registry Applications**

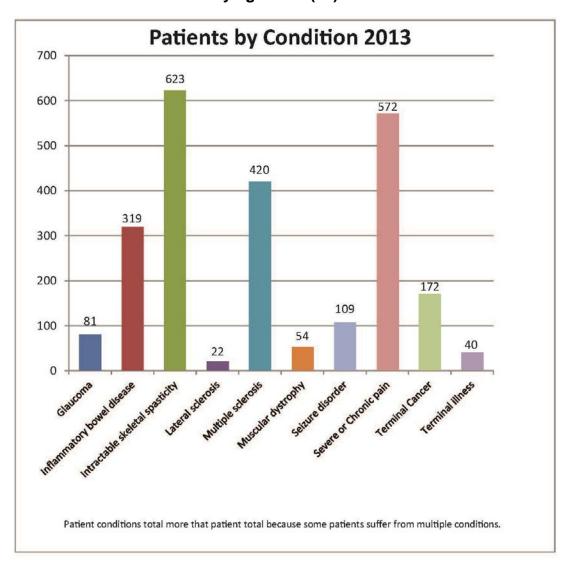
Registry Identification Cards Revoked

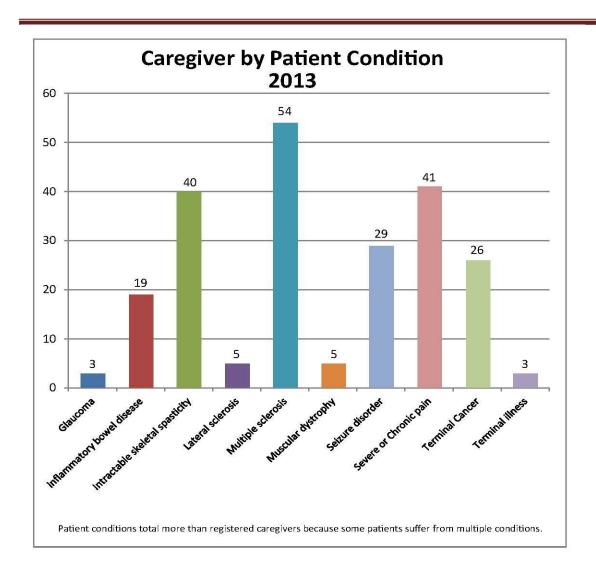
Patients Active Patients Inactive Patients Deceased Patients Disapproved Total Patient Applications	1,585 50 35 <u>2</u> 1,672
Qualifying Patients Registered*	1,670
<b>Caregiver Registry Applications</b>	
Caregivers Active	121
Caregivers Inactive	76
Caregivers Disapproved	0
Total Caregiver Applications	197
Primary Caregivers Registered*	197

0

<sup>\*</sup>Approximately 47% of registered patients and caregivers qualified and received the reduced application fee of \$20.00.

#### Nature of the Patients' Qualifying Illness(es)





Alternative Treatment Center Examinations	
Initiated	6
Completed	4
Ongoing	2
Alternative Treatment Center Permits	
Issued	3
Revoked	0
Physician Registry	
Physicians Active	250