



Department
of Health

Medical Use of Marijuana Under the **Compassionate Care Act**

TWO-YEAR REPORT



Introduction

On July 7th, 2014, Governor Andrew M. Cuomo signed into law the Compassionate Care Act to establish a comprehensive Medical Marijuana Program (“program”). Just eighteen months after the Compassionate Care Act was signed into law, the first New Yorkers obtained medical marijuana. The program launched on time and statewide, providing access to a new treatment option for patients in a manner that protects public health and safety. Within the first six months of operation, over 5,000 patients were certified with the program. The program also registered more than 600 physicians across the State. In just six months, New York’s program has more physicians registered than other states whose programs have been in existence for significantly longer than New York’s. The program continues to oversee the manufacture and sale of medical marijuana to ensure that it is dispensed and administered in a manner that protects public health and safety.

Pursuant to Public Health Law (PHL) § 3367(3), this report provides an overview of Medical Marijuana Program activities since the signing of the Compassionate Care Act, as well as recommendations to the Governor and the Legislature. The data for this report was obtained on June 15, 2016, from the New York State Department of Health’s (NYSDOH) Medical Marijuana Data Management System (MMDMS) and the Prescription Monitoring Program Registry (PMPR).

Medical Marijuana Program Implementation Timeline

- July 7, 2014:** The Compassionate Care Act is signed into Law by Governor Andrew M. Cuomo.
- December 31, 2014:** A notice of proposed rulemaking is published in the State Register, beginning the public comment period.
- February 17, 2015:** Public comment period ends for the proposed regulations. NYSDOH receives hundreds of public comments and completes an assessment of the public comments received.
- April 15, 2015:** A notice of adoption is published in the State Register. The Medical Marijuana Program regulations provide a framework for practitioner registration, patient certification, patient and caregiver registration, as well as requirements for registering organizations to manufacture, transport and sell medical marijuana within New York State based on the authority of the Compassionate Care Act.
- April 27, 2015:** NYSDOH begins accepting applications for registration as a registered organization from interested entities.
- June 5, 2015:** Deadline for NYSDOH receipt of completed applications for registration as a registered organization from interested entities.

- July 31, 2015:** Five applicants are selected to become registered organizations.
- October 20, 2015:** Four-Hour Medical Use of Marijuana course and practitioner registration system are launched, allowing practitioners to begin to register with the program.
- December 23, 2015:** Patient certification, patient registration, and caregiver registration system is launched, allowing practitioners registered with the program to begin certifying patients and allowing certified patients and designated caregivers to register and receive registry identification cards.
- January 7, 2016:** Registered organization dispensing facilities open across New York State.

Registered Organizations

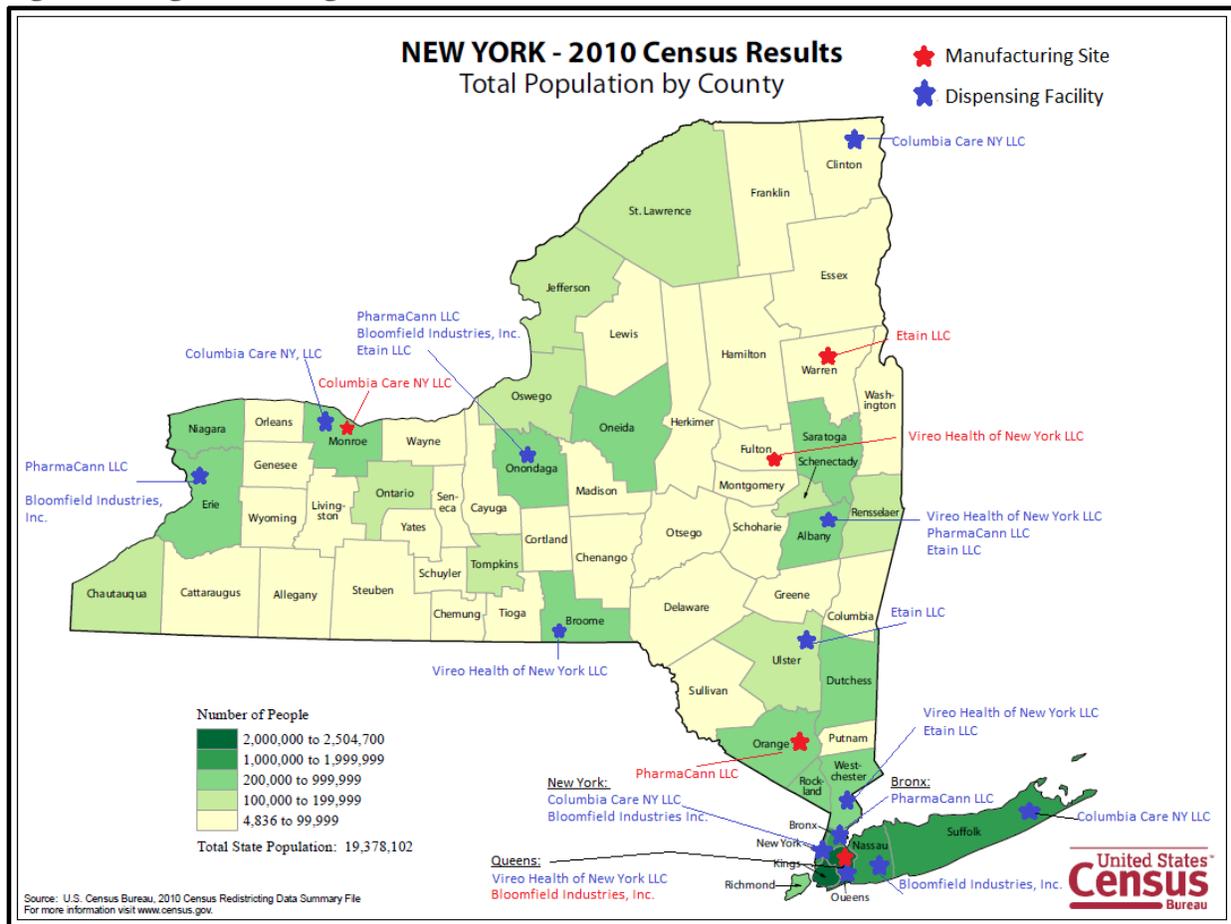
NYSDOH received 43 applications from entities interested in becoming registered organizations to manufacture and dispense medical marijuana under the Compassionate Care Act. NYSDOH evaluated all completed applications received on or before the deadline in accordance with the criteria set forth in PHL § 3365 and Title 10 of the New York Code of Rules and Regulations (NYCRR) §§ 1004.5 and 1004.6. On July 31, 2015, NYSDOH selected five applicants to become registered organizations. The five selected registered organizations, and their locations, are presented in Table 1 and Figure 1 below.

Table 1. Registered Organization Locations

Organization Name	Facility Type	Address	County
Bloomfield Industries Inc.	Manufacturing		Queens
	Dispensing	1304 Buckley Road, Syracuse, NY 13212	Onondaga
	Dispensing	52 South Union Road, Williamsville, NY 14221	Erie
	Dispensing	2001 Marcus Ave., Lake Success, NY 11042	Nassau
	Dispensing	Opening Soon	New York
Columbia Care NY LLC	Manufacturing		Monroe
	Dispensing	212 East 14 th Street, New York, NY 10003	New York
	Dispensing	345 Cornelia Street, Plattsburgh, NY 12901	Clinton
	Dispensing	200 West Ridge Rd., Rochester, NY 14615	Monroe
	Dispensing	1333 E. Main St., Riverhead, NY 11901	Suffolk
Etain, LLC	Manufacturing		Warren
	Dispensing	402 North Pearl Street, Albany, NY 12207	Albany
	Dispensing	445 State Route 28, Kingston, NY 12401	Ulster
	Dispensing	2140 Erie Boulevard, East Syracuse, NY 13224	Onondaga
	Dispensing	55 Main St., 2nd Floor, Yonkers, NY 10701	Westchester

PharmaCann LLC	Manufacturing		Orange
	Dispensing	25 Northpointe Parkway, Amherst, NY 14228	Erie
	Dispensing	642 Old Liverpool Road, Liverpool, NY 13088	Onondaga
	Dispensing	10 Executive Park Drive, Albany, NY 12203	Albany
	Dispensing	Opening Soon	Bronx
Vireo Health of New York LLC Formerly Known As Empire State Health Solutions	Manufacturing		Fulton
	Dispensing	221-223 E. Post Road, White Plains, NY 10601	Westchester
	Dispensing	89-55 Queens Blvd, Elmhurst, NY 11373	Queens
	Dispensing	589 Harry L Drive, Johnson City, NY 13790	Broome
	Dispensing	Opening Soon	Albany

Figure 1. Registered Organization Locations



Approved Medical Marijuana Products

Registered organizations are permitted to manufacture medical marijuana products in the following dosage forms:

- liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube;
- metered liquid or oil preparations for vaporization;
- capsules for oral administration;
- any additional form and route of administration approved by the commissioner.
- Smoking and edible products are not permitted.

Each registered organization may initially manufacture up to five brands of medical marijuana products and is required to offer one brand with an equal ratio of tetrahydrocannabinol (THC) to cannabidiol (CBD) and one with a low-THC to high-CBD ratio, among the initial five brands manufactured. In addition to the two required brands, registered organizations also offer brands that have varying ratios of THC to CBD. The registered organizations have worked aggressively to make a variety of brands in different dosage forms available to patients over the past several months. NYSDOH expects that additional brands and forms of administration will be offered over time as registered organizations continue to expand their operations. Brands are subject to change and NYSDOH may approve additional brands.

The regulations require that the testing of each “lot” of final medical marijuana product be conducted with a statistically significant number of samples using acceptable methodologies to ensure that all lots manufactured of each medical marijuana product are adequately assessed for contaminants and the cannabinoid profile (chemical contents of marijuana) is consistent throughout. Final cannabinoid profile testing includes the following cannabinoids: tetrahydrocannabinol (THC), tetrahydrocannabinol acid (THCA), tetrahydrocannabivarin (THCV), cannabidiol (CBD), cannabinadiolic acid (CBDA), cannabidivarin (CBDV), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), and any other cannabinoid component at > 0.1%. In addition, final products must be tested for various contaminants and pesticides.

All testing of medical marijuana products must be performed by an independent laboratory certified by the New York State Environmental Laboratory Approval Program (ELAP). The NYSDOH's Wadsworth Center is currently the only laboratory certified by ELAP to test medical marijuana products in New York State. Independent laboratories in New York State may apply for ELAP certification to perform testing of medical marijuana products for registered organizations in New York State.

Practitioner Registration

As set forth in 10 NYCRR § 1004.1(a), practitioners seeking to issue certifications for their patients to receive medical marijuana products must meet the following criteria:

- Be qualified to treat patients with one or more of the serious conditions set forth in PHL § 3360(7) or as added by the Commissioner;

- Be licensed, in good standing as a physician and practicing medicine, as defined in Article 131 of the Education Law, in New York State;
- Have completed a four-hour course approved by the Commissioner; and
- Have registered with NYSDOH.

On June 23, 2015, NYSDOH posted an advertisement in the New York State Contract Reporter seeking a vendor to provide an online continuing medical education (CME) course to physicians and pharmacists across New York State on the medical use of marijuana. TheAnswerPage, an established online medical education site which has provided medical education since 1998, was selected as the vendor.

On October 20, 2015, TheAnswerPage launched the NYSDOH approved four-hour course. The four-hour course includes the following topics: the pharmacology of marijuana; contraindications; side effects; adverse reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; and abuse and dependence. The cost of the online course is \$249, with the ability to earn 4.5 hours of CME upon successful course completion.

Practitioners began completing the four-hour course and registering with Medical Marijuana Program as early as October 21, 2015. Figure 2 below depicts the number of physicians registering each month from October 20, 2015 through June 15, 2016. Table 2 below represents the number of physicians registered with the program per county.

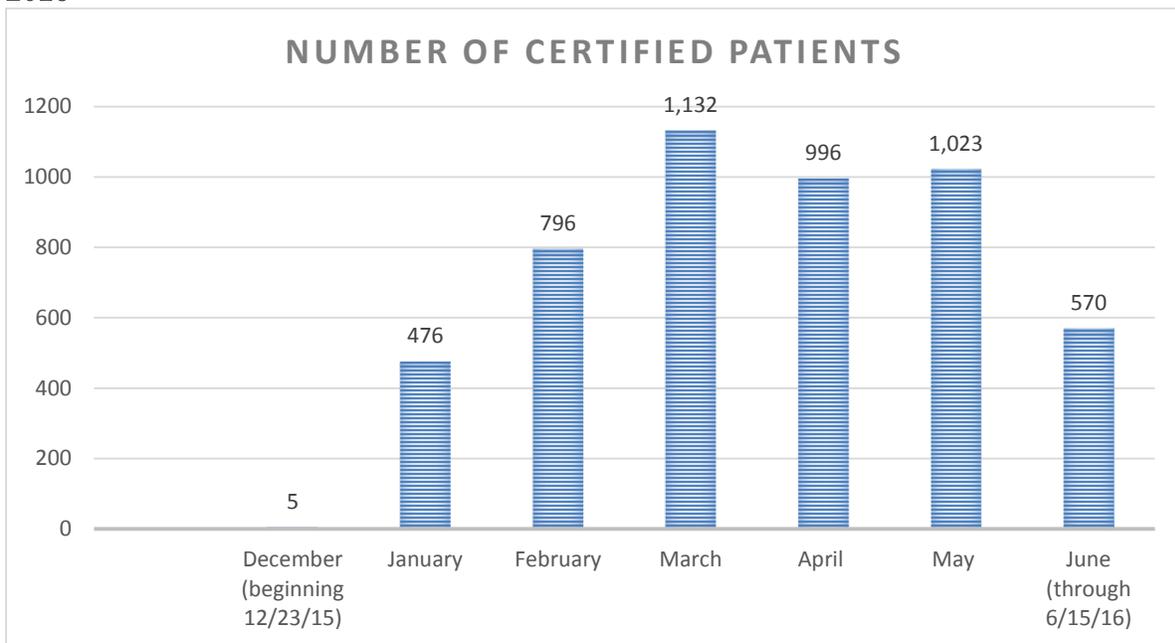
All physicians, as well as nurse practitioners and other licensed health care providers who are not registered with the program but who are qualified to treat the specified diseases and conditions enumerated by the Compassionate Care Act, may identify registered practitioners who have consented to be listed in the Medical Marijuana Data Management System. The list of consenting registered practitioners, including their specialties, is located online within the Department's Health Commerce System (HCS). The HCS is a web-based public health and immunization tracking system utilized by thousands of health care providers on a daily basis for a variety of applications. Most health care providers already have an HCS account and can therefore make a referral to a practitioner registered with the program by just logging on and accessing the available list.

The Department respects the physician-patient relationship and encourages patients to first consult with their own physicians, who have been treating them and are most familiar with their illness and symptoms, so they may agree that medical marijuana is an appropriate option. Medical marijuana should be a part of a patient's overall care plan and managed by the doctor treating the specified condition.

Patient Certification/Patient and Caregiver Registration

On December 23, 2015, the NYSDOH launched the Medical Marijuana Data Management System (MMDMS), which allows registered practitioners to certify patients to receive medical marijuana products. This electronic system is also used by certified patients to register with NYSDOH to receive a registry identification card. Certified patients must have a registry identification card to visit a registered organization's dispensing facility to obtain medical marijuana products. During the registration process, patients may designate up to two caregivers. Designated caregivers must also register with NYSDOH using MMDMS to be issued a registry identification card and visit dispensing facilities on behalf of registered patients. Figure 3 below depicts the number of patients certified each month from December 23, 2015, through June 15, 2016, the latest date through which data was available for this report. There were a total of 4,998 patients certified during this timeframe.

Figure 3. Number of new patients certified by month from December 23, 2015 to June 15, 2016



*Note: The data reflected in this graph represents unique certified patients.

Medical marijuana is available in New York for patients with the following severe, debilitating or life threatening conditions: cancer, HIV infection or AIDS, amyotrophic lateral sclerosis (ALS), Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, and Huntington's disease. Patients must also have one of the following clinically associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain, severe nausea, seizures, or severe or persistent muscle spasms.

Table 3 below depicts the certifications by age group for each severe debilitating or life-threatening condition defined in PHL § 3360(7)(a)(i). Table 4 below depicts the certifications by clinically associated condition or complication as defined in PHL § 3360(7)(a)(ii). The average

patient age across all certified patients is 52.08 years. Neuropathies represents the condition with the greatest percentage of certifications (34.09%). Severe or Chronic pain represents the associated condition with the greatest percentage of certifications (53.53%). Patients aged 51-60 years had the greatest percentage of certifications (25.51%).

Table 3. Patient certifications by age and qualifying condition from December 23, 2015 to June 15, 2016

Age	Cancer	HIV/AIDS	ALS	Parkinson's Disease	Multiple Sclerosis	Spinal Cord Injury	Epilepsy	IBD	Neuropathies	Huntington's Disease	Totals:
0-5	3	1	0	0	0	1	19	2	4	0	30 (0.60%)
6-12	6	0	0	0	0	0	35	7	2	0	50 (1.00%)
13-17	2	0	0	0	0	0	28	9	0	0	39 (0.78%)
18-30	50	10	0	0	35	42	105	105	112	1	460 (9.20%)
31-40	99	31	1	3	90	74	54	100	235	0	687 (13.75%)
41-50	182	34	2	9	139	99	41	58	354	1	919 (18.39%)
51-60	335	64	18	20	160	140	30	46	460	2	1275 (25.51%)
61-70	355	19	7	53	74	91	12	34	319	1	965 (19.31%)
71 +	206	6	5	54	16	53	4	11	218	0	573 (11.46%)
Totals:	1,238 (24.77%)	165 (3.30%)	33 (0.66%)	139 (2.78%)	514 (10.28%)	500 (10.00%)	328 (6.56%)	372 (7.44%)	1,704 (34.09%)	5 (0.10%)	4,998

*Note: The data reflected in this table represents unique certified patients and includes the primary qualifying condition from the certification.

Table 4. Number of patient certifications by clinically associated conditions or complications from December 23, 2015 to June 15, 2016

Month	Cachexia / Wasting Syndrome	Severe or Chronic Pain	Severe Nausea	Seizures	Severe or persistent muscle spasms
December (beginning 12/23/15)	2	3	0	2	0
January	89	338	62	47	123
February	119	560	152	82	248
March	136	861	181	78	336
April	105	748	152	71	293
May	110	803	152	55	328
June (through 6/15)	65	434	69	47	149
Totals:	626 (8.94 %)	3,747 (53.53%)	768 (10.97%)	382 (5.46%)	1,477 (21.10%)

*Note: Patients may be certified with more than one clinically associated condition or complication and therefore the data reflected in this table includes some certified patients more than once.

Pursuant to PHL § 3360(13), “terminally ill” means an individual has a medical prognosis that the individual’s life expectancy is approximately one year or less if the illness runs its normal course. A registered practitioner may indicate on a patient’s certification that, in the practitioner’s professional opinion, the patient is terminally ill and that the certification shall not expire until the patient dies. Table 5 below depicts the number of certified patients where the physician stated on the certification that the patient was terminally ill. As illustrated in the table,

13.79% of patients were issued certifications where the physician indicated that the patient was terminally ill.

Table 5. Number of new terminally ill certified patients per month.

Month	Cancer	HIV/AIDS	ALS	Parkinson's Disease	Multiple Sclerosis	Spinal Cord Injury	Epilepsy	IBD	Neuropathies	Huntington's Disease
December (beginning 12/23/15)	1	0	0	0	0	0	0	0	1	0
January	90	1	0	0	1	0	2	0	2	0
February	106	2	1	1	2	1	3	1	4	0
March	110	3	3	1	4	3	1	1	8	1
April	109	3	7	1	3	2	0	1	6	0
May	106	3	2	0	0	1	1	1	9	1
June (through 6/15/16)	67	0	3	0	1	0	3	0	5	0
Totals:	589 (85.49%)	12 (1.74%)	16 (2.32%)	3 (0.44%)	11 (1.60%)	7 (1.02%)	10 (1.45%)	4 (0.58%)	35 (5.08%)	2 (0.29%)

*Note: The data reflected in this table represents unique patients in each month.

Recognizing the importance of an efficient registration process to promote patient access, NYSDOH has worked to implement enhancements which have decreased the average time from certification to registration for patients since implementing the Medical Marijuana Data Management System for certifications and registrations on December 23, 2015. Although NYSDOH has up to 30 days from receipt of the registration application to approve, deny, or determine incomplete or inaccurate a patient's registration application, the average time from practitioner certification to patient registration approval has improved from 11.27 days to the current average of just 5.4 days (see Figure 4, below). It is important to note that not all patients choose to register on the same day they receive their certifications, impacting the average time from certification to registration. As of June 15, 2016, NYSDOH has approved 99.9% of the applications it has received from certified patients seeking to register with the program.

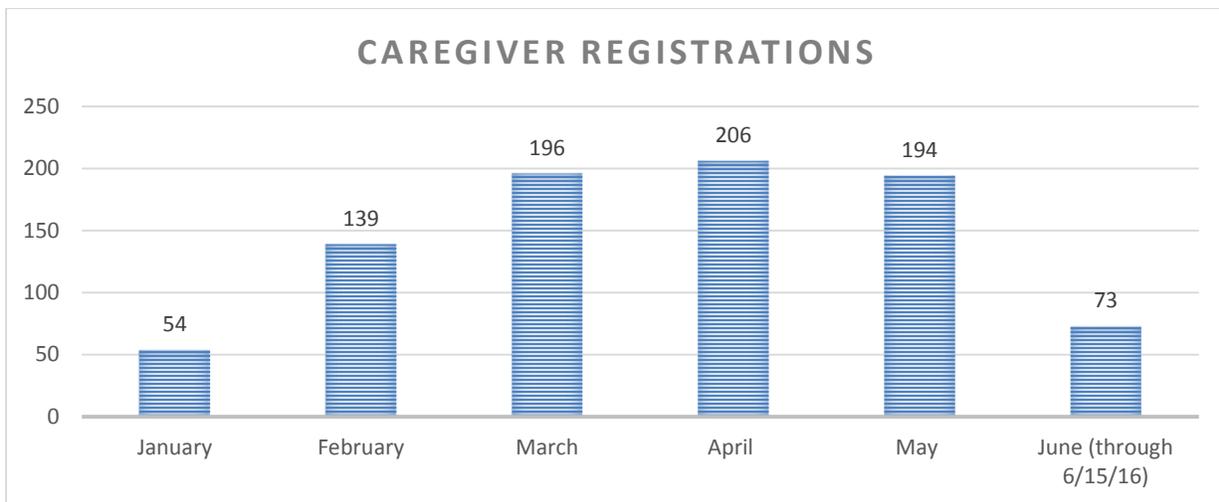
Figure 4. Average time from certification issued date to registration date (days)



*Note: The data reflected in this table represents the difference in days between the date the practitioner issued a certification to the patient and the date the patient registration became active.

A certified patient may designate up to two (2) caregivers during the patient registration process. Designated caregivers may assist the patient to obtain, possess, and administer medical marijuana. After a patient's application for registration is approved, a designated caregiver must also register with NYSDOH and receive a caregiver registry identification card before the caregiver may visit a dispensing facility on behalf of a registered patient. There were 862 designated caregivers registered from December 23, 2015 to June 15, 2016. Figure 5 below shows the number of caregivers registered by month during this time period. An individual may serve as a designated caregiver for up to five (5) registered patients. Of the 4,998 patients certified between December 23, 2015 and June 15, 2016, 608 have one designated caregiver and 127 have two designated caregivers.

Figure 5. Number of designated caregivers registered by month from December 23, 2015 to June 15, 2016

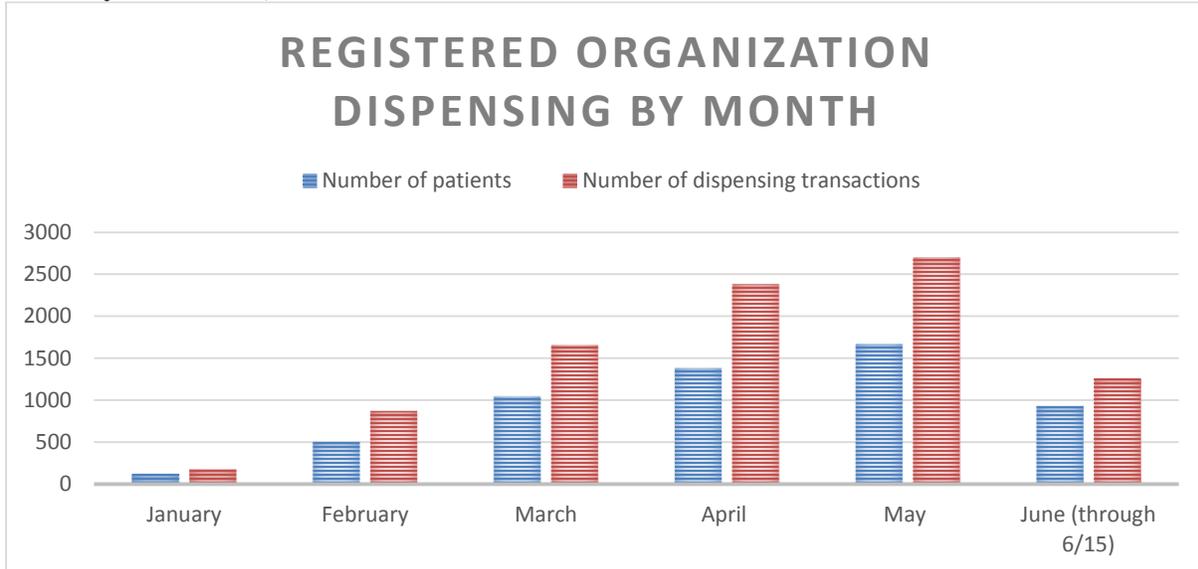


*Note: The data in this graph represents new caregivers in each month.

Dispensing Transactions

On January 7, 2016, eighteen months from the signing of the Compassionate Care Act, and just six months after being awarded their registrations, all five registered organizations opened a total of eight dispensing facilities across New York State. Currently, there are seventeen dispensing facilities open, with the remaining three facilities anticipated to open soon. Registered patients began obtaining medical marijuana products on the very first day of the program.

Figure 6. Number of unique patient visits and number of dispensing transactions from January 7–June 15, 2016



* Note: Complete data for the month of June was not available at the time this report was written. Dispensing transactions are greater than the number of patients because patients may purchase more than one product based on the recommendation from their registered practitioner or patients who may be starting or adjusting their dose may purchase a quantity that is less than a thirty day supply, which would result in an additional visit during a month.

Pricing

New York State Regulations require registered organizations to submit their manufacturing, marketing and distributing costs, and to certify that the information is accurate, complete and current. The Commissioner is then charged with determining the reasonableness of the proposed prices. The Commissioner reviewed the submitted prices from each registered organization and concluded that based on their business plans, production costs and anticipated sales volumes, and assuming reasonable economy and efficiency, that the registered organizations proposed prices were reasonable. NYSDOH approved a maximum price per dose, meaning registered organizations are permitted to reduce the price of their medical marijuana products at any time.

NYSDOH’s approved prices are in effect for the entire period of the registered organization’s registration, until July 30, 2017. However, at the conclusion of the first year of the registration period, or prior to that date based on documented exceptional circumstances, registered organizations may request a price modification. In addition, if a Registered Organization adds a new product, it must submit revised production costs and other relevant data, along with the proposed price for the new product(s) to the Department for review and approval.

The total amount that a patient pays for a particular medical marijuana product depends upon a patient’s individual dosing needs and the resultant total quantity purchased. For an accurate estimate of current product prices, patients should contact the registered organizations directly. In addition, all registered organizations offer reduced-price programs which may help to lower the cost of medical marijuana for qualifying patients.

Recommendations and Next Steps

1. NYSDOH recommends authorizing Nurse Practitioners (NPs) to certify New Yorkers for medical marijuana, consistent with their current authority to prescribe controlled substances (including opioids) for patients diagnosed with qualifying conditions covered in the Compassionate Care Act. Allowing NPs to issue certifications for medical marijuana would allow them to properly treat patients suffering from severe, debilitating or life threatening conditions, particularly in many rural counties where there are fewer physicians available to treat such ailments. Additionally, NYSDOH will continue outreach and education efforts to practitioners in order to improve their understanding of the medical marijuana program and the availability of this additional treatment option for qualifying patients.
2. NYSDOH recommends exploring ways to make it easier for healthcare facilities and schools to possess, secure, and administer medical marijuana products under limited circumstances necessary to safeguard the health of registered patients.
3. NYSDOH recommends making several general amendments to the regulations to enhance the program, including but not limited to: streamlining manufacturing requirements and broadening the capability for registered organizations to advertise their participation in the program.
4. NYSDOH recommends evaluating allowing distribution of Medical Marijuana to certified patients through home delivery services provided by registered organizations, and review of policies and procedures from other jurisdictions to help craft guidelines to provide for a safe and effective home delivery program. NYSDOH will also continue to monitor the volume of patients and dispensing trends to ensure adequate patient access to medical marijuana products.
5. NYSDOH recommends working with the registered organizations to make more brands of medical marijuana products available to patients. In addition, NYSDOH will continue to evaluate scientific and technological developments that support the addition of new routes and forms of administration of medical marijuana products.
6. NYSDOH recommends continuing outreach to encourage the easing of federal restrictions on and impediments to scientific research on the potential benefits of medical marijuana, as well as the Registered Organizations' ability to conduct financial transactions and establish traditional banking relationships.
7. NYSDOH recommends a review of evidence be conducted for the medical use of marijuana in patients suffering from chronic intractable pain. NYSDOH will also continue its effort to identify and acknowledge evidence for the medical use of marijuana for additional conditions that are not currently qualifying conditions enumerated by the Compassionate Care Act.
8. NYSDOH anticipates identifying opportunities to enhance the practitioner, patient and caregiver certification and registration system, including enhancements to the Medical Marijuana Data Management System.

9. To meet additional patient demand and increase access to medical marijuana throughout New York State, NYSDOH recommends registering five additional organizations over the next two years, using a phased-in approach to permit their smooth integration into the industry.
10. NYSDOH recommends that independent laboratories in New York State apply for ELAP certification to perform testing of medical marijuana products for registered organizations in New York State to keep up with the growing demand for such testing.
11. NYSDOH recommends expanding the financial hardship waiver for the \$50 patient and caregiver application fee for registration.
12. NYSDOH recommends streamlining and enhancing the practitioner registration process, to make it easier for practitioners to register with the program. NYSDOH will explore additional ways in which to ensure that patients have access to registered practitioners, including adding a public list of consenting practitioners registered with the program and enhancing the list of registered practitioners currently available through the HCS. NYSDOH also plans to build into the registration system a method for practitioners to consent to being listed publicly and plans to reach out to those practitioners already registered with the program to determine whether they would consent to being listed publicly.