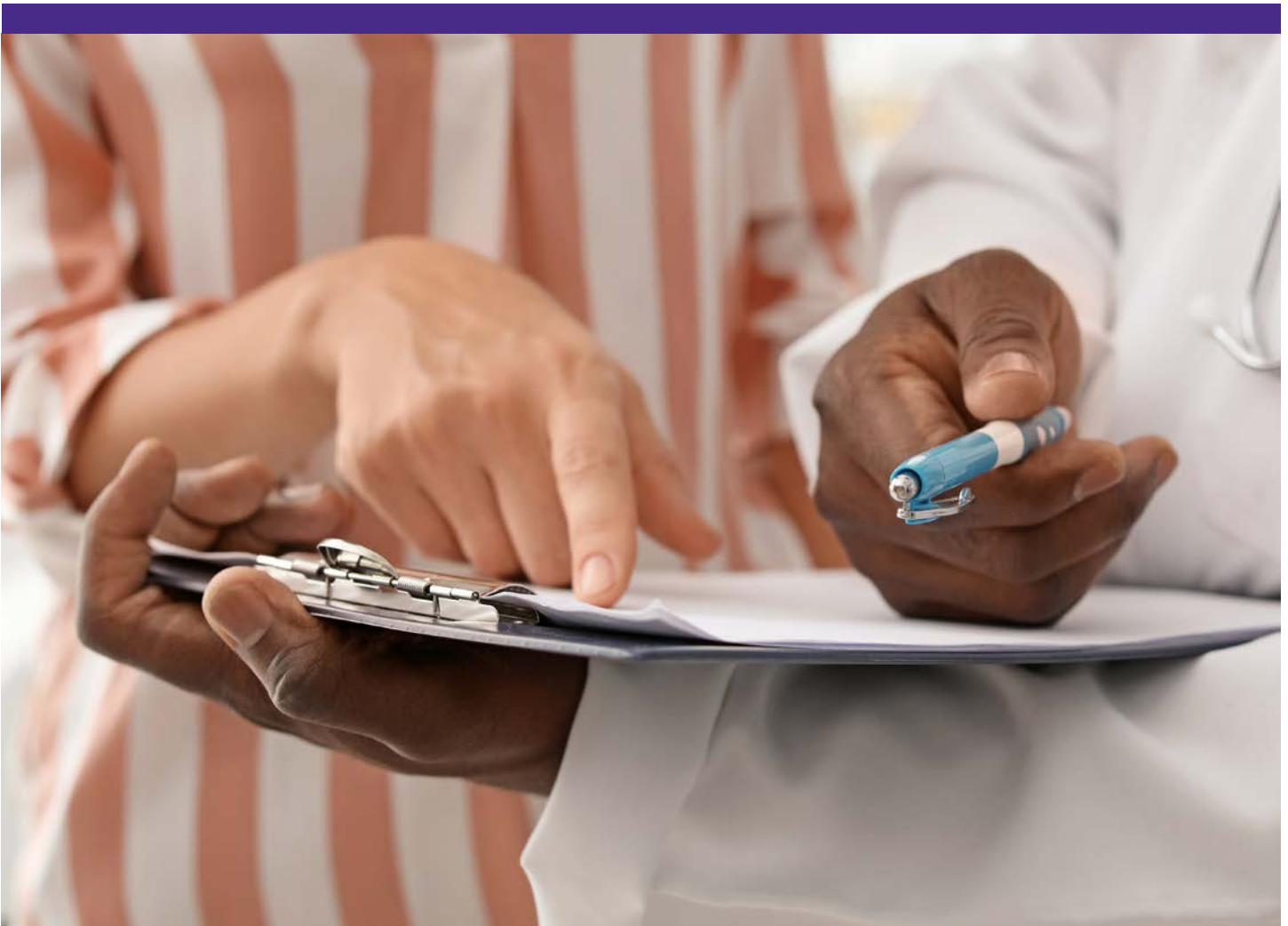




Department  
of Health

# Medical Use of Marijuana Under the Compassionate Care Act



**TWO-YEAR REPORT**

## Table of Contents

Introduction .....	2
Program Highlights Since the Previous Two-Year Report: .....	2
Practitioner Registration .....	3
Figure 1. Number of Registered Practitioners by Calendar Quarter.....	4
Figure 2. Registered Practitioners and Certified Patients by County as of June 30, 2018 .....	5
Patient Certification .....	5
Figure 3. Number of New Patients Certifications and Cumulative Patient Certifications for Each Calendar Quarter .....	6
Table 1. Patient Certifications by Age and Qualifying Condition, December 23, 2015 through June 30, 2018 ....	7
Table 2. Number of Patient Certifications by Clinically-Associated Conditions or Complicating Conditions, December 23, 2015 - June 30, 2018 .....	7
Table 3. Number of Patients Certified as Terminally Ill by Age Group .....	8
Patient and Caregiver Registration .....	8
Figure 4. Total Designated Caregivers Registered by Calendar Quarter .....	9
Dispensing Transactions .....	10
Figure 5. Number of unique patient visits and dispensing transactions by quarter .....	10
Figure 6. Percentage of Returning Patients .....	11
Registered Organizations.....	11
Figure 7. Registered Organization Dispensing Facility Locations .....	12
Table 4. Medical Marijuana Products Available as of June 30, 2018 .....	13
Pricing of Approved Medical Marijuana Products .....	14
Insurance Coverage for Approved Medical Marijuana Products .....	14
Product Testing and Adverse Event Reporting .....	15
Recommendations and Next Steps .....	15

## **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 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. Since the implementation of the program, a number of improvements have been made to better serve patients suffering from serious conditions in New York State. Program improvements include the authorization of nurse practitioners and physician assistants to certify patients for medical marijuana, increasing the number of organizations registered to manufacture and dispense medical marijuana, expanding the list of qualifying conditions to include chronic pain, post-traumatic stress disorder and any condition for which an opioid may be prescribed, allowing registered organizations to wholesale to other registered organizations, and allowing registered organizations to deliver medical marijuana products to the homes of patients or their caregivers. These efforts, along with those of the registered organizations and practitioners who participate in the program, contributed to an overall increase of 1,124% in the number of certified patients in the past two years.

Pursuant to Public Health Law (PHL) § 3367(3), this report provides an overview of the program’s activities since the last two-year report was published, as well as recommendations and proposed next steps to the Governor and the Legislature. The data within the figures and tables for this report were obtained through June 30, 2018, from the NYSDOH Medical Marijuana Data Management System (MMDMS) and the Prescription Monitoring Program Registry (PMPR).

On July 13, 2018, the New York State Department of Health (NYSDOH) released its report on the assessment of the potential impact of regulated marijuana in New York State. It concluded that the positive effects of a regulated marijuana market in New York State outweigh the potential negative impacts. As neighboring states continue to implement recreational marijuana programs and New York State considers the implementation of a regulated adult-use marijuana program, it is critical for New York’s medical marijuana program to expand access to reach more patients suffering from severe debilitating or life-threatening conditions who may benefit from medical marijuana. The recommendations highlighted in this report are aimed at expanding the State’s medical marijuana program, which employs high quality manufacturing and quality assurance standards, in a manner that continues to protect the public health and safety.

### **Program Highlights Since the Previous Two-Year Report:**

**September 7, 2016:** NYSDOH issued guidance permitting registered organizations to begin delivering approved medical marijuana products to the homes of certified patients and their designated caregivers.

**November 30, 2016:** NYSDOH adopted regulations allowing nurse practitioners to register with the program to certify patients.

- December 8, 2016:** NYSDOH issued guidance permitting registered organizations to wholesale medical marijuana extracts and approved medical marijuana products to other registered organizations in New York State.
- March 15, 2017:** NYSDOH adopted regulations allowing physician assistants to register with the program to certify patients.
- March 22, 2017:** NYSDOH adopted regulations adding chronic pain as a serious condition for which patients may be certified to use medical marijuana.
- June 22, 2017:** NYSDOH streamlined the practitioner registration process, allowing practitioners to register online and certify patients on the same day. A public list of registered practitioners was also introduced to the NYSDOH medical marijuana program website.
- August 1, 2017:** NYSDOH renewed the registration of five registered organizations and registered five additional organizations to manufacture and dispense medical marijuana products in New York State.
- October 5, 2017:** NYSDOH adopted emergency regulations allowing facilities to act as designated caregivers.
- December 27, 2017:** NYSDOH adopted regulations to enhance the program for patients, practitioners and registered organizations.
- July 12, 2018:** NYSDOH adopted emergency regulations adding any condition for which an opioid may be prescribed as a serious condition for which patients may be certified to use medical marijuana.
- July 13, 2018:** NYSDOH introduced temporary registry identification cards to expedite access for certified patients and designated caregivers.

### **Practitioner Registration**

To issue medical marijuana certifications to patients, practitioners must first complete a NYSDOH approved education course and then register with the program. TheAnswerPage was the first online course provider approved by NYSDOH. On July 6, 2017, a second provider, The Medical Cannabis Institute, launched an approved online medical use of marijuana course. This offers practitioners another option when selecting an online course to complete. To further expand the educational options available to practitioners, NYSDOH introduced regulations, that took effect on December 27, 2017, reducing the course requirement from a four-hour minimum to a two-hour minimum. NYSDOH is working to make additional course offerings available to practitioners.

When the program was first implemented in January 2016, only physicians were authorized to register with the program to certify patients for medical marijuana. To help increase the availability of practitioners, NYSDOH adopted regulations on November 30, 2016, to allow nurse practitioners to register with the program to certify patients. On March 15, 2017, regulations were adopted to allow physician assistants to register with the program, provided that the physician assistant is under the supervision of a physician already registered with the program. The addition of nurse practitioners and physician assistants contributed to a 33.2% increase in available practitioners statewide. As of June 30, 2018, nurse practitioners and physician assistants comprised 21.6% of all practitioners in the program.

On June 22, 2017, a couple of important improvements were made regarding registered practitioners and the program. First, NYSDOH streamlined the MMDMS, an online application used to process practitioner registrations, to allow practitioners to register online and immediately begin certifying patients the same day. Prior to this enhancement, the practitioner registration process took several days to complete, meaning practitioners had to wait several days before they could begin certifying patients for medical marijuana. In addition, NYSDOH began publishing a list of consenting registered practitioners on its medical marijuana program website, which helps patients find a practitioner registered with the program. The publicly available list supplements the list of practitioners available on the NYSDOH Health Commerce System (HCS), which can be used by certain health care providers with an HCS account to allow them to refer patients to a practitioner registered with the program and has been available since February 2016.

**Figure 1** below depicts the number of practitioners registered by calendar quarter from the fourth quarter of 2015 through the second quarter of 2018. **Figure 2** below represents the number of practitioners registered with the program per county and includes the number of patients with active certifications per county.

**Figure 1. Number of Registered Practitioners by Calendar Quarter**





**Figure 3. Number of New Patients Certifications and Cumulative Patient Certifications for Each Calendar Quarter**



*Note: As of June 30, 2018, there was a total of 61,198 patients with active certifications. Figure 3 above represents the number of new patients certified each calendar quarter, along with the cumulative total for each calendar quarter. Patient certifications may be canceled or expire, which is why the total number of patient certifications is higher than the number of active certifications.*

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, Huntington's disease, chronic pain, Post-Traumatic Stress Disorder (PTSD) and as a replacement to prescription opioids. Chronic pain was added by NYSDOH as a qualifying condition through regulations adopted on March 22, 2017. PTSD was added through legislation on November 11, 2017. Most recently, NYSDOH introduced emergency regulations, which went into effect on July 12, 2018, adding any condition for which an opioid may be prescribed. In addition to a severe debilitating or life-threatening condition, patients must also have one of the following clinically associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain resulting in substantial limitation of function, severe nausea, seizures, severe or persistent muscle spasms, PTSD, or opioid use disorder, but only if enrolled in a treatment program certified pursuant to Article 32 of the Mental Hygiene Law.

**Table 1** below depicts the certifications by age group for each severe debilitating or life-threatening condition. **Table 2** below depicts the certifications by clinically associated or complicating condition. The most common severe debilitating or life-threatening condition is chronic pain (53.13%). The most common clinically associated or complicating condition is severe or chronic pain (72.93%). Patients aged 51-60 years made up the greatest percentage of certifications (23.06%), followed by patients aged 61-70 (19.21%).

**Table 1. Patient Certifications by Age and Qualifying Condition, December 23, 2015 through June 30, 2018**

Age	Amyotrophic Lateral Sclerosis	Cancer	Chronic Pain	Damage to Nervous Tissue of the Spinal Cord	Epilepsy	Huntington's Disease	Inflammatory Bowel Disease	Multiple Sclerosis	Neuropathies	Parkinson's Disease	Positive Status for HIV/AIDS	PTSD	Total	%
0-5		59	119	8	72		10	6	35	1	7	3	320	0.33%
6-12		34	21	3	233		68		9			3	371	0.38%
13-17		41	77	2	194		105		21			7	447	0.46%
18-30	2	322	5,120	259	805		915	168	747	3	86	732	9,159	9.34%
31-40	10	674	9,018	511	543	3	904	712	1,802	9	220	872	15,278	15.57%
41-50	23	1,432	9,872	674	345	6	642	920	2,527	44	205	485	17,175	17.51%
51-60	66	2,832	12,249	894	248	8	502	1,285	3,621	183	366	367	22,621	23.06%
61-70	87	3,529	9,152	668	128	1	365	855	3,169	505	170	214	18,843	19.21%
71+	55	3,029	6,490	479	37	4	146	228	2,381	952	31	55	13,887	14.16%
<b>Total:</b>	<b>243</b>	<b>11,952</b>	<b>52,118</b>	<b>3,498</b>	<b>2,605</b>	<b>22</b>	<b>3,657</b>	<b>4,174</b>	<b>14,312</b>	<b>1,697</b>	<b>1,085</b>	<b>2,738</b>	<b>98,101</b>	
<b>%</b>	<b>0.25%</b>	<b>12.18%</b>	<b>53.13%</b>	<b>3.57%</b>	<b>2.66%</b>	<b>0.02%</b>	<b>3.73%</b>	<b>4.25%</b>	<b>14.59%</b>	<b>1.73%</b>	<b>1.11%</b>	<b>2.79%</b>		

\*Note: Patients may have more than one qualifying condition; however, the data reflected in this table represents unique certified patients and includes only the primary condition listed on each certification.

**Table 2. Number of Patient Certifications by Clinically-Associated Conditions or Complicating Conditions, December 23, 2015 - June 30, 2018**

Age	Cachexia or Wasting Syndrome	PTSD	Seizures	Severe Nausea	Severe or Chronic Pain	Severe or Persistent Muscle Spasms	Total	%
0-5	19	5	73	34	163	26	320	0.33%
6-12	10	2	236	17	66	40	371	0.38%
13-17	16	6	210	37	154	24	447	0.46%
18-30	141	752	850	600	5,977	839	9,159	9.34%
31-40	176	944	571	727	11,005	1,855	15,278	15.57%
41-50	242	569	427	795	12,827	2,315	17,175	17.51%
51-60	486	444	322	1,179	17,105	3,085	22,621	23.06%
61-70	739	278	205	1,117	13,993	2,511	18,843	19.21%
71+	891	84	81	787	10,257	1,787	13,887	14.16%
<b>Total:</b>	<b>2,720</b>	<b>3,084</b>	<b>2,975</b>	<b>5,293</b>	<b>71,547</b>	<b>12,482</b>	<b>98,101</b>	
<b>%</b>	<b>2.77%</b>	<b>3.14%</b>	<b>3.03%</b>	<b>5.40%</b>	<b>72.93%</b>	<b>12.72%</b>		

A registered practitioner may state 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. 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. **Table 3** below depicts the number of certified patients designated as terminally



ill on their certification. As illustrated in **Table 3**, 5,026 patients, or 5.12% were issued certifications where the physician indicated that the patient was terminally ill.

**Table 3. Number of Patients Certified as Terminally Ill by Age Group**

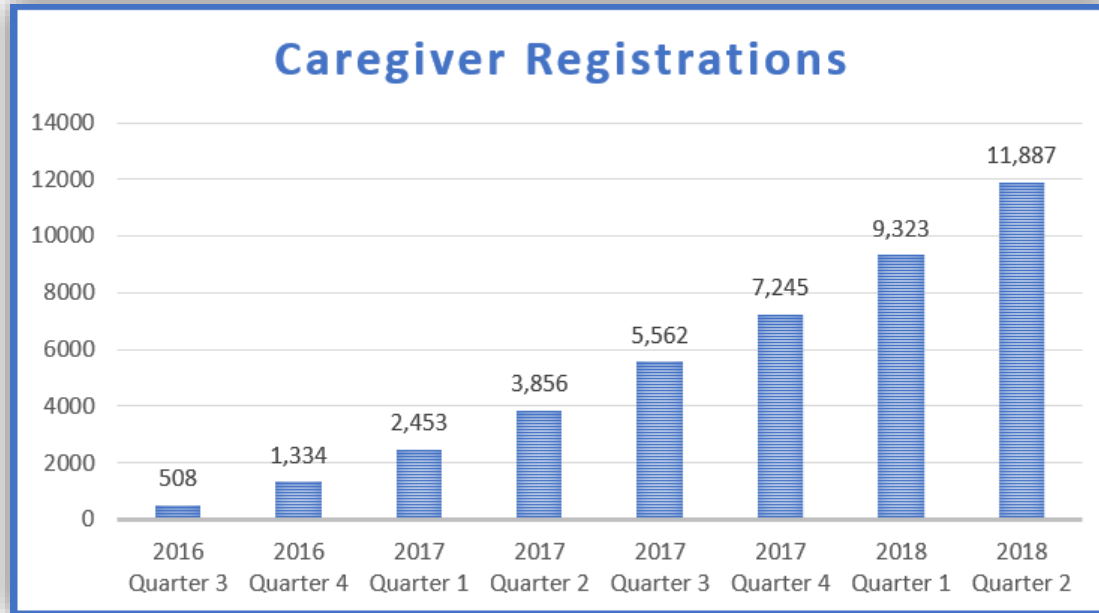
Age	Amyotrophic Lateral Sclerosis	Cancer	Chronic Pain	Damage to Nervous Tissue of the Spinal Cord	Epilepsy	Huntington's Disease	Inflammatory Bowel Disease	Multiple Sclerosis	Neuropathies	Parkinson's Disease	Positive Status for HIV/AIDS	PTSD	Total
0-5		30	2	2	4				1		1		40
6-12		18			6				1				25
13-17		20			16				1				37
18-30		78	7	1	15		1	2	4		1	1	110
31-40	4	159	21	2	8			1	4		3	3	205
41-50	7	349	30		4	1	2	5	11	1	3	1	414
51-60	25	913	76	4	2	1	2	14	31	3	17	1	1,089
61-70	38	1,290	95	10	7	1	1	4	18	17	5	3	1,489
71+	14	1,421	101	6	3			1	34	31	1	1	1,617
<b>Total:</b>	<b>88</b>	<b>4,278</b>	<b>332</b>	<b>25</b>	<b>65</b>	<b>3</b>	<b>7</b>	<b>30</b>	<b>105</b>	<b>52</b>	<b>31</b>	<b>10</b>	<b>5,026</b>

**Patient and Caregiver Registration**

The MMDMS is used by certified patients, and their designated caregivers, to register with NYSDOH to receive a registry identification card. Certified patients and designated caregivers must have a registry identification card to purchase approved medical marijuana products from registered organization dispensing facilities and must have the card with them whenever they are in immediate possession of medical marijuana. After completing registration, it can take seven to ten business days for patients or caregivers to receive their registry identification cards. To expedite access, eliminate the waiting period and more quickly bring relief to suffering patients, on July 13, 2018, NYSDOH introduced temporary registry identification cards for certified patients and designated caregivers.

A certified patient may designate up to two caregivers during the patient registration process. Designated caregivers may assist up to five patients in obtaining, possessing, and administering medical marijuana. After a patient's registration is approved, a designated caregiver must also register with NYSDOH and receive a caregiver registry identification card. **Figure 4** below shows the number of new caregiver registrations by calendar quarter.

**Figure 4. Total Designated Caregivers Registered by Calendar Quarter**



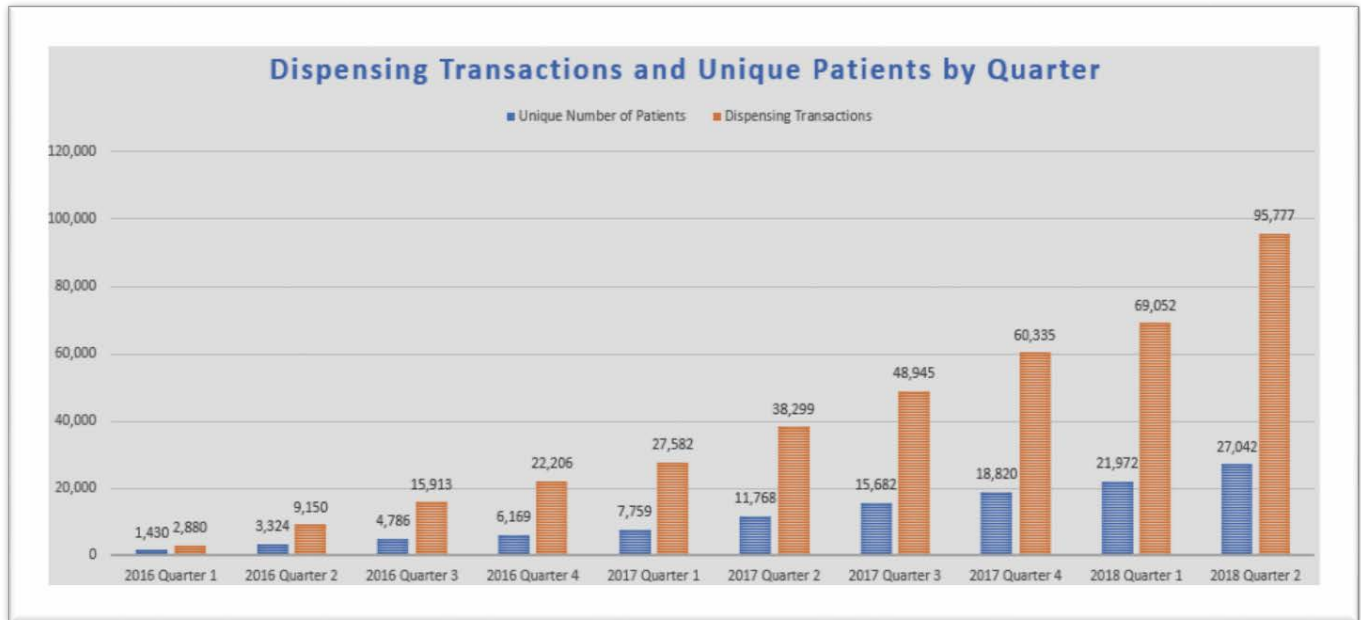
PHL § 3362 authorizes the possession, acquisition, use, delivery, transfer, transportation or administration of medical marijuana by a certified patient or designated caregiver, possessing a valid registry identification card, for certified medical use. Recognizing that patients suffering from serious conditions may be hospitalized, reside in a treatment facility, or attend school during the course of their illnesses, NYSDOH worked to identify a way to assist medical marijuana patients to continue their courses of therapy in these situations. On October 5, 2017, NYSDOH introduced emergency regulations allowing patients to designate certain defined facilities as a designated caregiver. These regulations provide facilities the ability to assist patients with the acquisition, transportation, possession, administration and storage of approved medical marijuana products. Facility participation is optional. Since the introduction of the emergency regulations, the Department has approved thirteen facility caregiver registrations, including registrations for hospitals, residential health care facilities, and assisted living facilities. In addition, three registration requests were denied for failure to meet the registration requirements. Information regarding the process for designated caregiver facilities, including the Facility Caregiver Designation Form, can be found on NYSDOH's program website using the following link: [http://health.ny.gov/regulations/medical\\_marijuana/caregiver/](http://health.ny.gov/regulations/medical_marijuana/caregiver/).

There exists the opportunity to improve the continuity of patient care, add legal clarity, and reduce bureaucratic processes if the Department could eliminate the process of facility caregiver registration through a legislative amendment to the Compassionate Care Act that specifically empowered certain staff of hospitals, schools, and other expressly authorized facilities, under certain circumstances, to obtain, possess, store, and administer medical marijuana products on behalf of patients, as they may for certain other medications.

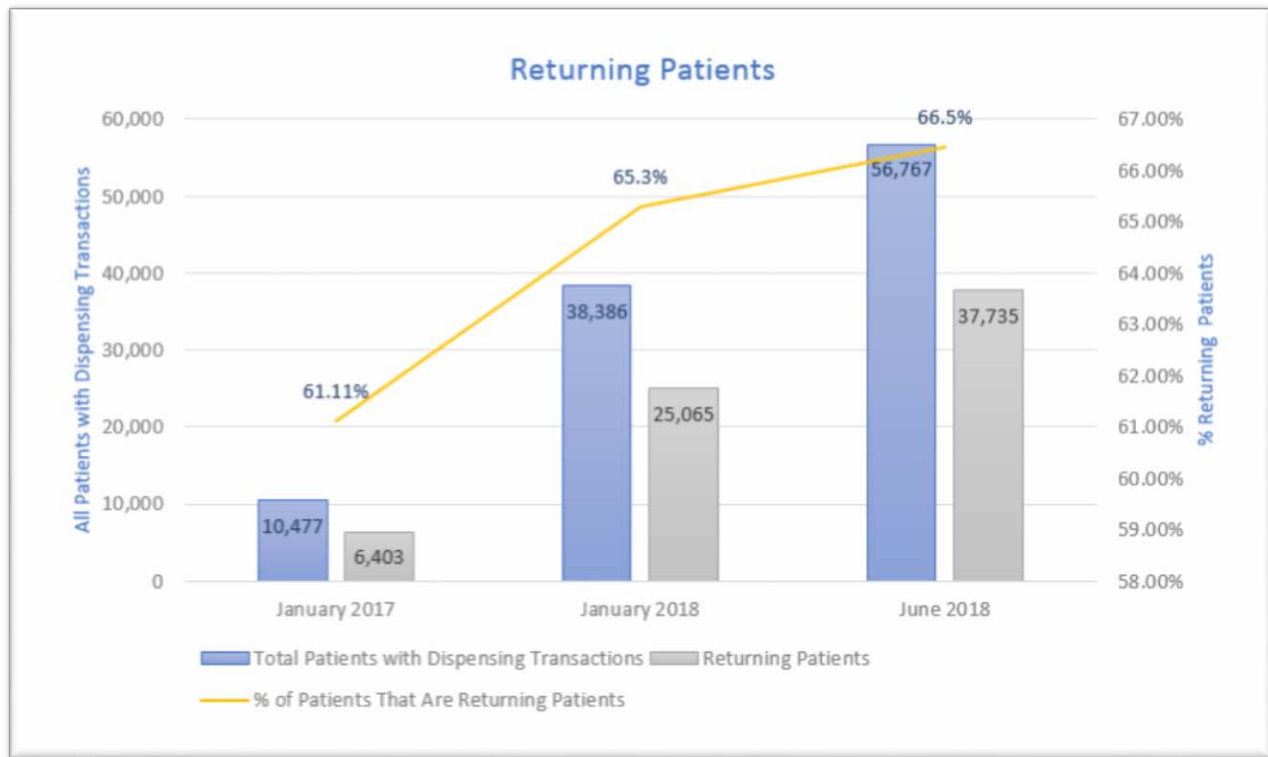
## Dispensing Transactions

Registered organizations must submit their medical marijuana product dispensing data to NYSDOH's PMPR within 24-hours of dispensing. **Figure 5** below shows the total number of dispensing transactions by calendar quarter. **Figure 6** below provides the percentage of patients who went on to purchase additional medical marijuana products after their first dispensing transaction. Patients may only purchase medical marijuana products once for a variety of reasons, including, but not limited to, product cost, product efficacy, death of the patient, or distance to a dispensing facility.

**Figure 5. Number of unique patient visits and dispensing transactions by quarter**



**Figure 6. Percentage of Returning Patients**

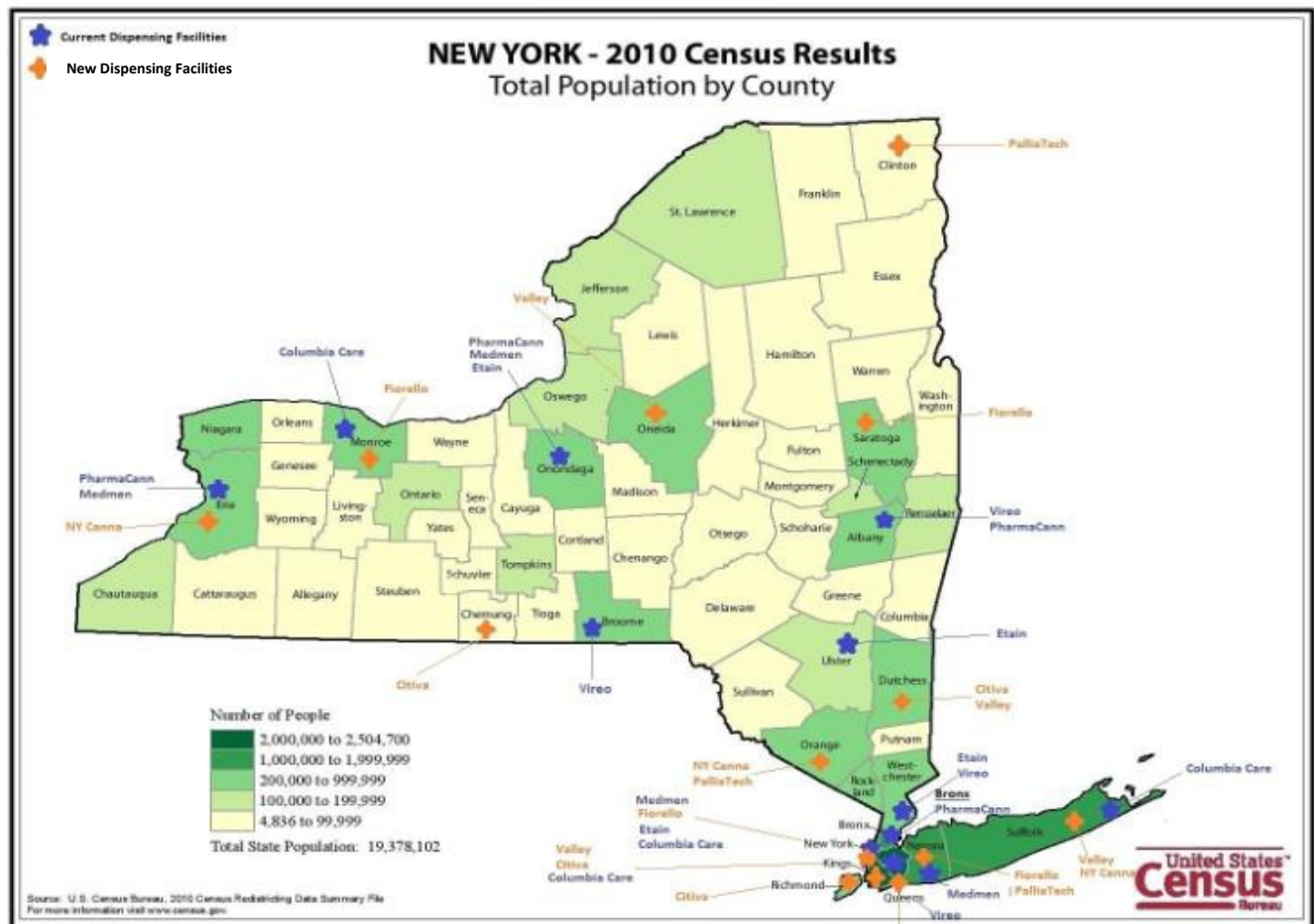


In addition to medical marijuana dispensing transactions, all Schedule II–V controlled substances dispensed to patients are captured within NYSDOH’s PMPR. NYSDOH conducted an analysis of certain PMPR data to evaluate the effect of opioid use in patients receiving medical marijuana in New York State. NYSDOH is working towards publishing the results of this analysis.

**Registered Organizations**

On August 1, 2017, NYSDOH renewed the registration of the five organizations who were originally registered on July 31, 2015. In addition, NYSDOH registered five more organizations on August 1, 2017, to improve patient access, increase the variety of medical marijuana products available and help make products more affordable through the introduction of new competition. NYSDOH continues to work with the registered organizations as they submit various requests to NYSDOH requiring review and approval, including delivery plans, wholesale plans, new product proposals, pricing proposals, facility updates, and relocation amendments. During this two-year reporting period, NYSDOH conducted a total of 66 site visits to get new and relocated facilities operational since the last reporting period. Since the program’s inception, DOH has conducted a total of 199 site visits. The location of the ten registered organizations, and their dispensing facilities, are presented in **Figure 7** below.

**Figure 7. Registered Organization Dispensing Facility Locations**



To help expand access for patients, NYSDOH issued guidance on September 7, 2016, permitting registered organizations to deliver approved medical marijuana products to the homes of registered patients and their designated caregivers. As of June 30, 2018, Columbia Care NY LLC, PharmaCann LLC, and Vireo Health of New York LLC are approved to provide delivery services in New York State. Patients interested in delivery service should contact registered organizations directly to obtain additional information.

In addition, NYSDOH issued guidance on December 8, 2016, permitting registered organizations to wholesale medical marijuana extracts and approved medical marijuana products to other registered organizations in New York State. As of June 30, 2018, Columbia Care NY LLC, Etain LLC, and PharmaCann LLC are approved to wholesale products to other registered organizations in New York State.

At the onset of the program, registered organizations were only permitted to manufacture medical marijuana products in liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube; metered liquid or oil preparations for vaporization; and capsules for oral administration. NYSDOH amended regulations on December 27, 2017, to allow registered organizations to manufacture products in additional dosage forms, including: topicals; patches; solid and semisolid preparations (examples include suppositories, capsules, chewable tablets, lozenges);

and metered ground plant preparations. Any additional forms and routes of administration must be approved by the commissioner. Smoking and some edible products are not permitted. Below is a table of the products that are available to patients as of June 30, 2018. Brands are subject to change and NYSDOH may approve additional brands. Products available to patients as of June 30, 2018 are shown in **Table 4**, below.

**Table 4. Medical Marijuana Products Available as of June 30, 2018**

Registered Organization	Brand	Dosage Forms Available	THC/CBD Ratio
<b>Columbia Care NY</b>	CCNY 1T:1C	Capsule, Sublingual Drops, Vape Pen	Equal THC and CBD <sup>2</sup>
	CCNY 20T:1C	Capsule, Sublingual Drops, Tablet, Vape Pen	High THC : Low CBD
	CCNY 1T:20C	Capsule, Sublingual Drops, Tablet, Vape Pen	Low THC : High CBD <sup>1</sup>
<b>Etain</b>	Balance	Capsule, Oral Spray, Powder for Ingestion, Tincture, Vape Pen	Equal THC and CBD <sup>2</sup>
	Forte	Capsule, Oral Spray, Powder for Ingestion, Tincture, Vape Pen	High THC : Low CBD
	Forte Lite	Tincture	High THC : Low CBD
	Dolce	Capsule, Oral Spray, Vape Pen, Tincture	Low THC : High CBD <sup>1</sup>
	Dolce XL	Capsule, Tincture	Low THC : High CBD <sup>1</sup>
	Mezzo	Capsule, Tincture, Oral Spray	CBD Dominate
<b>MedMen</b>	LuxLyte Wellness	Gel Capsules, Oral Drops	Low THC : High CBD <sup>1</sup>
	LuxLyte Harmony	Disposable Vape Pen, Gel Capsules, Oral Drops	Equal THC and CBD <sup>2</sup>
	LuxLyte Awake	Disposable Vape Pen, Gel Capsules, Oral Drops	High THC : Low CBD
	LuxLyte Calm	Disposable Vape Pen, Gel Capsules, Oral Drops	High THC : Low CBD
	LuxLyte Sleep	Disposable Vape Pen, Gel Capsules, Oral Drops	High THC : Low CBD
<b>PharmaCann</b>	Blue	Capsule, Extra Strength Capsule, Tincture, Vape Cartridge	High THC : Low CBD
	Green	Capsule, Extra Strength Capsule, Tincture, Vape Cartridge	Equal THC and CBD <sup>2</sup>
	Yellow	Oral Solution, Tincture, Vape Cartridge	Low THC : High CBD <sup>1</sup>
	Lime	Tincture, Vape Cartridge	CBD Dominate
	Aqua	Tincture, Vape Cartridge	THC Dominate
<b>Vireo Health</b>	Indigo	Capsules, Oral Solution	Low THC : High CBD <sup>1</sup>
	Blue	Bulk Vape Oil Syringe, Capsules, Prefilled Vape Cartridge, Oral Solution	CBD Dominate
	Green	Bulk Vape Oil Syringe, Capsules, Prefilled Vape Cartridge, Oral Solution	Equal THC and CBD <sup>2</sup>
	Yellow	Bulk Vape Oil Syringe, Capsules, Prefilled Vape Cartridge, Oral Solution	THC Dominate
	Red	Bulk Vape Oil Syringe, Capsules, Prefilled Vape Cartridge, Oral Solution	High THC : Low CBD
	Red/Yellow/Green Starter Pack	Capsules & Prefilled Vape Cartridge	High THC : Low CBD THC Dominate Equal THC and CBD <sup>2</sup>

<sup>1</sup> Product that meets regulatory requirement set out in Title 10 NYCRR § 1004.11(c)(4) with low THC and high CBD content.

<sup>2</sup> Product that meets regulatory requirement set out in Title 10 NYCRR § 1004.11(c)(5) with approximately equal amounts of THC and CBD.

NYSDOH has been actively reviewing product and pricing submissions, as well as other standard operating procedure updates, as the five new registered organizations continue to phase in their operations. PalliaTech dba Curaleaf has begun manufacturing operations in their Albany County facility, and has begun dispensing operations in their Clinton County, Orange County, and Queens County dispensing facilities by supplying PharmaCann products through a wholesale agreement. NYCANNA has begun manufacturing operations in their Onondaga County manufacturing facility. NYSDOH continues to make progress with the new five registered organizations and anticipates having additional dispensing facilities operational.

### **Pricing of Approved Medical Marijuana Products**

NYSDOH has been working to improve affordability of medical marijuana products for patients. Recent efforts to improve affordability include the adoption of regulations on December 27, 2017, allowing for additional lower cost dosage forms to be manufactured. Pursuant to PHL § 3369-d, every sale of medical marijuana must be at the price determined by the commissioner of NYSDOH. The commissioner has approved a maximum price per milligram dose for each product offered by the registered organizations; however, registered organizations are permitted to reduce the price of their medical marijuana products at any time and can offer discount programs to patients. Patients should contact the registered organizations directly to obtain the most current pricing information. NYSDOH will continue to work on enhancements to help reduce costs and plans to thoroughly examine each registered organization's approved pricing prior to registration renewal.

### **Insurance Coverage for Approved Medical Marijuana Products**

Pursuant to PHL § 3368, insurance providers under the PHL or New York State Insurance Law are not required to offer coverage for medical marijuana. However, nothing within the PHL prohibits an insurer from including medical marijuana as a covered medication. Based upon recent decisions of the New York State Workers' Compensation Board (WCB), patients receiving workers' compensation benefits in New York State may be reimbursed for the cost of medical marijuana if the following criteria are met:

- The patient is certified to use medical marijuana by a registered practitioner who is WCB authorized per WCL § 13-b;
- The medical marijuana is used to treat a condition authorized under Public Health Law § 3360(7) and DOH regulations (10 NYCRR 1004.2[a][8]);
- The condition for which the patient is certified is related to an established site of injury in a workers' compensation claim;
- The treating practitioner has obtained a **variance** if the condition is addressed in the applicable WCB medication treatment guidelines (MTGs) **OR** the treating medical provider has obtained a **C-4AUTH** approval if the medical marijuana cost exceeds \$1,000 and the treatment is for a body part or condition not covered by the MTGs; and
- The claimant submits a request for medical marijuana reimbursement as a Medical & Travel (M&T) reimbursement request.

Practitioners certifying patients who receive workers' compensation benefits should review the criteria above and work with WCB to assist patients in obtaining coverage, when appropriate. NYSDOH will continue to work with WCB to support with education and outreach concerning the availability of and process for coverage.

### **Product Testing and Adverse Event Reporting**

All medical marijuana products produced by registered organizations must be tested by an independent laboratory, certified by the NYSDOH Environmental Laboratory Approval Program (ELAP). The NYSDOH Wadsworth Center conducts testing pursuant to 10 NYCRR §§ 1004.11 and 1004.14, which includes testing of each "lot" of final medical marijuana product to assess for contaminants and cannabinoid profile (chemical contents of marijuana). Since the Wadsworth Center's Medical Marijuana Laboratory initiated testing of final medical marijuana products in December of 2015, the laboratory has received 799 lots from registered organizations and tested 4,420 samples. NYSDOH's Wadsworth Center is currently the only laboratory certified by ELAP to test medical marijuana products in New York State; however, NYSDOH is currently seeking independent laboratories in New York State to undertake medical marijuana product testing and encourages commercial laboratories within the state to apply for the required ELAP certification to conduct this testing.

NYSDOH monitors adverse events related to medical marijuana products. The Adverse Event Reporting Tool is a survey administered through the Person-based Electronic Response Data System (PERDS) which users can access through the HCS. The Adverse Event Reporting Tool is used to track adverse events related to medical marijuana products or devices and to help the program identify potential public health risks through the information reported. Adverse event reporting instructions may be accessed by clicking the "Practitioners Information" tab on the medical marijuana program webpage. Since the program was implemented on January 7, 2016, a total of 35 adverse events were reported to the Department. Of the 35 adverse events reported, no adverse events resulted in a fatality. One adverse event was categorized by the person reporting the event as a serious event requiring hospitalization. Sixteen of the patients discontinued use of the product due to the adverse event.

### **Recommendations and Next Steps**

The purpose of the Compassionate Care Act is to comprehensively regulate the manufacture, sale and use of medical marijuana while striking the right balance between potentially relieving the pain and suffering of those in desperate need of a treatment and protecting the public against risks to its health and safety. NYSDOH recommends expanding the medical marijuana program to reach patients who may be self-medicating with marijuana from sources that are not regulated or held to the same high-quality standards as the medical marijuana products manufactured by registered organizations in New York State. The steps below will help to achieve this goal.

1. NYSDOH recommends affording practitioners more clinical discretion in determining whether or not to certify patients for medical marijuana, based on an evaluation of the patient's condition, past treatment and the overall risks versus benefits for each patient.



2. Currently, only physicians, nurse practitioners and physician assistants can register with NYSDOH to certify patients to use medical marijuana. To increase the number of practitioners available to certify patients, NYSDOH recommends permitting all prescribers of controlled substances to humans to participate in the program.
3. NYSDOH will implement regulatory amendments to support research studies of approved medical marijuana products, allow registered organizations to use third party contractors for security, and make other regulatory amendments to continue to enhance the program.
4. NYSDOH recommends allowing researchers in New York State, with proper Institutional Review Board approval or Institutional Animal Care and Use Committee approval, the ability to apply for licensure to acquire, possess, store or administer medical marijuana. This would allow researchers to conduct clinical and basic research involving medical marijuana and lawfully possess medical marijuana on behalf of patients for the purpose of research without being designated as a caregiver by the patient.
5. NYSDOH recommends a pilot study with one or more third party payors to demonstrate the effects on consumption and costs in patients who are taking medical marijuana in New York State.
6. NYSDOH will continue to work with the New York State Workers' Compensation Board to assist patients in obtaining coverage for medical marijuana expenses, and to educate practitioners and patients on the process for obtaining reimbursement for medical marijuana.
7. NYSDOH will continue to enhance the MMDMS to further simplify the process for practitioners, patients and caregivers.
8. NYSDOH recommends increasing the number of caregivers for each certified patient to five caregivers per patient, allowing increased flexibility for families in providing care to their loved ones.
9. NYSDOH recommends implementing an initiative to educate practitioners and the public on the benefits of medical marijuana and the program, while aiming to deter self-medication through recreational marijuana use.